Vol. 44—No. 14
1-19-79
BOOK 1:
PAGES
3943-4174

BOOK 2:
PAGES
4175-4430

federal register

BOOK 2 OF 2 BOOKS
FRIDAY, JANUARY 19, 1979
PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

IMPROVING GOVERNMENT REGULATIONS

Publication of Semiannual Agenda

[4110-12-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

IMPROVING GOVERNMENT REGULATIONS

Semiannual Agenda of Regulations

AGENCY: Department of Health, Education, and Welfare.

ACTION: Publication of the semiannual agenda of regulations (Improving Government Regulations).

SUMMARY: The President's Executive Order on Improving Government Regulations, Executive Order 12044, requires each Federal agency to publish at least twice a year a list of significant regulations under development. HEW published its first semiannual agenda in the May 30, 1978 FEDERAL REGISTER. This semiannual agenda contains: (1) *all* non-FDA regulations being developed within the Department; and (2) FDA regulations classified as "policy significant." The Department plans to publish its next semiannual agenda by June 30, 1979.

ADDRESS: For inquiries or comments related to specific regulations listed in the agenda, the public is encouraged to contact the appropriate responsible individual. Questions or comments concerning the overall agenda should be sent to Rick Cotton, Executive Secretary to the Department of Health, Education, and Welfare, 200 Independence Avenue, S.W., Washington, D.C., 20201.

Dated: January 2, 1979.

JOSEPH A. CALIFANO, Jr.,
Secretary.

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	*RA	CONTACT
Adult Education (NPRM)	Policy Significant	Adult Education Act, P.L. 91-230, as amended by Education Amendment of 1978. P.L. 95-561	Regulations are needed to provide uniform interpretation and implementation of the law.	The regulations will expand the current delivery system of adult education and will broaden the outreach of the program.	No	Paul V. Delker, Adult Edu. Prog., Office of Education, 7th & D Sts., S.W., Washington, D.C., (202) 245-2278
Metric Education (NPRM)	Technical	Sec. 403 of P.L. 93-380, as amended by the Education Amendments of 1978. P.L. 95-561	Need to clarify program purpose, objectives, and funding criteria.	The regulations will establish criteria for evaluation of grants to prepare students, parents and other adults to use the metric system.	No	Floyd Davis, Metric Education, Prog., U.S. Office of Education, 831 Riviera Bld., 1832 M. St., N.W. Washington, D.C. 20202 (202) 653-5811
Consumers' Education (NPRM)	Policy Significant	Sec. 811 of P.L. 93-380, as amended by the Education Amendments of 1978. P.L. 95-561	Need to clarify standards and establish uniform evaluation criteria.	Develop the capacity of Education institutions and community agencies to provide consumers' education to persons of all ages.	No	Dustin W. Wilson, Jr., Office of Consumers' Ed., Office of Education 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 653-5983
Community Education (NPRM)	Policy Significant	Sec. 405 of P.L. 93-380, as amended by the Education Amendments of 1978. P.L. 95-561	Regulations are needed to clarify the law.	The regulations will expand the scope and responsibilities of the present community education program.	No	Julie Englund, Community Education Program, Office of Education, 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-0691
Youth Employment (NPRM)	Policy Significant	Sec. 627 of Education Amendments of 1978. P.L. 95-561	Regulations are needed to interpret and clarify the law.	Regulations will establish requirements to prepare children to take their place as working members of society.	No	Sid High, Office of Career Education, U.S. Office of Education, 7th & D Sts., S.W., Washington, D.C. 20202 (202) 245-2335

*RA - Regulatory Analysis (Yes/No)

Basic Skills Improvement Program (R2R) (NPRM)	Policy Significant	Title II & Title IX, Part B, Education Amendments of 1978 (P. L. 95-561)	Law in general terms in the two applicable titles thereby requiring clarification.	Expands National Reading Improvement Act Program affecting all States, LEAs, and many non-public schools.	No	Tom Keyes, Program Officer, Office of Education, 400 Maryland Ave., S.W., Washington, D.C. 20202 (202) 245-2710
Gifted & Talented (NPRM)	Technical	Education Amendments of 1978 (P.L. 95-561)	Required to incorporate changes of Ed. Amendments of 1978 and write in simple English.	Revised the present regulations to provide interested parties, a better understanding of the program.		Dr. Dorothy Sisk, Director, Office of Gifted & Talented, Office of Education 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-2482
Handicapped Children Early Education Program (NPRM)	Technical	Education Amendments P.L. 94-142	Law in general terms and require clarification to include all age groups. Also write in simple English.	Provides funds for Handicapped children's Early childhood Education.	No	Dr. William Swan, Division of Innovation & Development, BEH, Rm. 3120, Donohoe Bldg. 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-9722
Indian Education Program (NPRM)	Policy Significant	Ed. Amendment of 1978 P.L. 95-561	Law in general terms, needs to clarify existing regulations.	Supports all phases of Indian Education children and adults.	No	Dr. John Tippeconic U.S. Office of Education Rm. 2177, FOB-6 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-8020
Handicapped Media Services (NPRM)	Technical	Ed. Amendment of 1977 P.L. 95-49	Incorporate minor language change and write in simple English.	The regulations govern the administration of programs which provides a free loan service of captioned films for the deaf and promotes the educational and cultural advancement of handicapped persons through research and the use of media and technology.	No	Barry E. Katz, U.S. Office of Education Rm. 4819, Donohoe Bldg. 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 472-4640

General Provisions Relating to Student Assistance Program (FINAL)	Policy Significant	Section 497-A of the Higher Education Act of 1965, as amended (P.L. 94-482)	Statute in general terms - implementing provisions need regulation (NPRM pub. 8/10/78)	This regulation will establish fiscal and administrative standards for institutions participating in	No	William L. Moran Chief, Basic Grants Policy Section, OPPD/ BSFA/OE, Rm. 4318, ROB-3 400 Maryland Ave., S.W. Washington, D.C. 20202
1979-1980 Basic Grant Family Contribution Schedule (FINAL)	Technical	Sec. 411(a)(3)(A)(i) of the Higher Edu. Act of 1965, as amended (P.L. 94-482)	Statute requires the annual publication of the Family Contribution Schedule (NPRM pub. 8/14/78)	The Family Contribution Schedules are the formula used in determining eligibility on the basis of financial need for the Basic Educational Opportunity Grants Program.	No	Same as above
Basic Educational Opportunity Grant Program-Administrative and Technical (FINAL)	Technical	Sec. 411 of the Higher Education Act of 1965, as amended (P.L. 94-482)	New regulations which revise and consolidate existing program regulations and incorporate applicable provisions of the Education Amendments of 1976 and the Middle Income Student Assistance Act (NPRM pub. 5/15/78)	These regulations govern institutional administration of the Basic Grant Program, computation of awards, and all other areas of program administration except the Family Contribution Schedules.	No	Same as above
HEAL (NPRM)	Policy Significant	Title VII, Part C, Subpart 1, PHS Act as amended (P.L. 94-484, P.L. 95-83, P.L. 95-215)	To implement three major provisions of law never regulated before.	This regulation will esta- requirements for non-student borrowers, withholding of Federal reimbursement for health services from defaulted HEAL loans for service in health manpower shortage areas.	No	David Bayer, Acting Chief, GSL Branch, BSFA, Rm. 4002, ROB-3, 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-9717

GSL (503) Interest Benefits & Special Allowance (FINAL)	Policy Significant	Higher Education Act of 1965 as amended (20 U.S.C. 1071-1087-4) (P.L. 94-482)	Regulations required by Sec. 503 of the Education Amendments of 1972 (P.L. 92-318) Implementing changes to current regulations required by the Ed. Amendments of 1976 (P.L. 94-482) Middle Income Student Assistance Act (P.L. 95-566)	This regulation will establish reguirements for the GSLP.	No	David Bayer, Acting Chief, GSL Branch BSFA, Rm. 4002, ROB-3 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-9717
NDSL, CWS, & SEOG (NPRM)	Technical	HEA of 1965 (P.L. 94-482)	Law in general terms implementing instructions needed.	This regulation will change institutional application procedures for the campus-based programs. Public comment has been requested on the NPRM.	No	Tom Butts, Special Assist. to Deputy Commissioner for BSFA, Rm. 4662, ROB-3 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-0231
NDSL, CWS, & SEOG (FINAL)	Technical	HEA of 1965 (P.L. 94-482)	Need to finalize an Interim Regulation and rewrite in plain English.	The regulations govern the administration of three programs of assistance to students with financial need to achieve the benefits of post-secondary education.	No	Norman Brooks, Acting Chief Policy Section, Campus-Based Branch, BSFA, Rm. 4018, ROB-3 7th & D Sts., S.W. Washington, D.C. 20202 (202) 245-9720

Ethnic Heritage Studies (NPRM)	Technical	The Elementary and Secondary Act of 1965, as amended by the Ed. Amendments of 1972, 1974, and 1978	Technical changes needed in the existing regulations and to simplify and revise the criteria.	This regulation will improve the existing criteria for eligibility and for selection of applicants for grants.	No	Stanley Wilcox, Acting Chief, Ethnic Heritage Studies Branch, U.S. Office of Education Rm. 3913, ROB-3 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-2761
Law School Clinical Experience Program (NPRM)	Policy Significant	Title XI of the HEA of 1965 as amended by P.L. 90-575, 92-318, 94-482	Program was initially authorized for one year (1978). Funds have been appropriated for FY 1979.	This regulation provides rules for establishing and expanding programs in law schools to provide clinical experience to students in the practice of law.	No	Donald Bigelow, Bureau of Higher and Continuing Education, (Rm. 3060) ROB-3, 400 Maryland Ave., S.W., Washington, D.C. 20202 (202) 245-2347
Institutional Eligibility (NPRM)	Policy Significant	HEA of 1965, as amended	To clarify procedures currently used by the Agency to determine the eligibility of postsecondary institutions. These procedures are being used but they have not been published.	This regulation will establish the procedures that the Commissioner of Education uses to determine the eligibility status of postsecondary institutions.	No	John R. Proffitt, Director of Eligibility and Agency Evaluation, BHCE, U.S. Office of Education, Rm. 3030, ROB-3, Washington, D.C. 20202 (202) 245-9873
Criteria for Recognition of National Accrediting Bodies and State Approval Agencies (NPRM)	Policy Significant	Veterans Readjustment Assistance Act of 1952, plus 23 other statutory authorities including P.L. 92-318	Simplify and revise the criteria.	This regulation will establish the Commissioner's procedures for selecting nationally recognized accrediting agencies who are reliable authorities concerning the quality of education or training offered by educational institutions or programs they evaluate.	No	Same as above

Title I, ESEA Evaluation (FINAL)	Policy Significant	P.L. 93-380 as amended by P.L. 95-561	Law requires Commissioner to mandate evaluation models and standards.	This regulation establishes models and standards for the evaluation of Title I projects.	May Not Be Decided	Dr. Judith Burnes, OPBE, U.S. Office of Education, Rm. 3049, 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-8364
National Diffusion Network (NPRM)	Policy Significant	Ed. Amendments of 1978 P.L. 95-561	Law requires program changes.	These regulations govern the selection of projects and establish criteria for awards.	No	Dr. Andrew M. Lebby Office of Education Rm. 3616, ROB-3 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-9582
Arts Education (NPRM)	Policy Significant	The Arts Education Act of 1978	Required by law to broaden eligibility requirements.	These regulations govern the selection of all grantees and some contractors establish eligibility requirements, and criteria.	No	Dr. Harold Arberg Office of Education Rm. 3728, Donohoe Bldg. 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 472-7793
Education Division General Provisions Regulations (NPRM)	Policy Significant	P.L. 92-318 as amended by Ed. Amendments of 1978 - P.L. 95-561	Recodification under Operation Common Sense and to implement Ed. Amendments of 1978.	These regulations govern all fiscal and administrative requirements for the Education Division programs.	No	Dr. Marcel DuVall Office of Education 400 Maryland Ave., S.W. Rm. 508, Reporters Bldg. Washington, D.C. 20202 (202) 472-7773
Women's Educational Equity Act Program (NPRM)	Policy Significant	Women's Educational Equity Act of 1978	Implement the law establishing criteria and priorities.	These regulations will establish criteria and priorities for financial assistance to provide educational equity for women in the U.S.	No	Dr. Mary Jane Smalley Women's Program Staff Office of Education Rm. 2147, FOB-6 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-2181

Law-Related Education (NPRM)	Policy Significant	Education Amendments of 1978, P.L. 95-561	Law requires the Commissioner to award grants and contracts to provide law-related education programs.	Purpose is to encourage SEAs and LEAs and other public and non-profit agencies, organizations, and institutions to provide law-related education programs.	No	Mr. Steven Winnick Office of Education 400 Maryland Ave., S.W. Rm. 4091 Washington, D.C. 20202 (202) 245-8953
Bilingual Education (INTERIM FINAL)	Policy Significant	Education Amendments of 1978, P.L. 95-561	To implement requirements emanating from Pub. L. 95-561.	The interim regulation establish criteria to determine English language proficiency levels of eligible children, provide parental participation, information for provision of training under a basic program, pre-inservice training, and repayment or work criteria to fellowship recipients, and evaluation criteria.	No	Ms. Barbara J. Wells Office of Education 400 Maryland Ave., S.W. Rm. 421, Reporters Bldg. Washington, D.C. 20202 (202) 447-9273
Bilingual Education (NPRM)	Policy Significant	Same as above	To implement the law.	Will establish standards and procedures for eligibility requirements, definitions, program requirements, evaluation procedures, and use of funds.	No	Same as above
Education Hearing Board (NPRM)	Policy Significant	Commissioners policy and The Education Amendments of 1978 P.L. 95-561	Extend the jurisdiction of the Title I ESEA Audit Hearing Board and implement requirements of the law.	These proposed regulations establish an Education Hearing Board to provide imperative administrative procedures for resolution of adverse monetary audit findings for State-administered programs.	No	Dr. David Pollen Office of Education 400 Maryland Ave., S.W. Rm. 4051 Washington, D.C. 20202 (202) 245-7836

SAFA - School Construction-Amendments Sec. 10 (NPRM)	Policy Significant	P.L. 81-815, as amended	A Departmental decision requires regulatory changes to implement new program priorities.	Regulations to determine LEAs ability to provide suitable free public education and change priorities to include major renovation or new construction to meet life safety and accessible to handicapped standards.	No	Dr. William W. Chase Office of Education 400 Maryland Ave., S.W. Rm. 2067 Washington, D.C. 20202 (202) 245-8412
SAFA - Technical Amendments-Maintenance and Operation (FINAL)	Policy Significant	P.L. 81-874, as amended	To incorporate changes recommended by GAO and others to improve administration of the program	These regulations incorporate certain requirements governing the awarding of Federal assistance to school districts enrolling certain categories of children receiving free public education in areas affected by Federal assistance. They will establish uniform determination of eligibility for those who work on Federal property.	No	Mr. William Stormer Office of Education 400 Maryland Ave., S.W. Rm. 2107-A Washington, D.C. 20202 (202) 245-8427
Library Services and Construction Act Amendments (FINAL)	Technical	P.L. 95-123	Required by Law.	Establish rules for matching Federal funds, change base year for maintenance of effort requirements for handicapped; and add emphasis to major urban resource libraries.	No	Mrs. Elizabeth H. Hughey Office of Education 400 Maryland Ave., S.W. Rm. 3119-B, ROB-3 Washington, D.C. 20202 (202) 472-5150
Correction Education (NPRM)	Policy Significant	Correction Education Demonstration Project Act of 1978, Title III, Secs. 371-374 of Part J of the Education Amendments of 1978, P.L. 95-561	Statute is very general. Implementing institutions needed.	These regulations will establish application eligibility and requirements and selection criteria for applicants for support under the Act.	No	James Spillane, U.S. Office of Education Rm. 2047, FOB-6 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-7292

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	*RA	CONTACT
Educational Improvement, Resources, and Support (NPRM)	Policy Significant	Amendment to Title IV of the Elementary and Secondary Education Act of 1965 (P.L. 95-561)	The statute sets general policy; major important implementir provisions need regulation. Also, the Department has set new policies which require modification of the regulations.	The regulation will establish requirements for State administration of programs for acquisition of instructional materials and school library resources; for the improvement in local educational practices; and for guidance, counseling, and testing.	No	Louise V. Sutherland School Media Resources Branch, Bureau of Elementary and Secondary Education, USOE, 400 Maryland Avenue, S.W., Washington, D.C. 20202, (202) 245-2488
Indochina Refugee Children Assistance Act (NPRM)	Policy Significant	The Education Amendments of 1978, Title XIII, Part C, Sec. 1331	Provision of educational services to Indochinese refugee children and guidance for SEA program administration	These regulations will establish requirements for LEA's and SEA's regarding educational services for Indochinese refugee children.	No	James H. Lockhart Director, IRTF HEW/OE FOB-6, Rm. 2189 400 Maryland Ave., S.W. Washington, D.C. 20202 (202) 245-3081

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	RA	CONTACT
Financial Assistance for Environmental Education Projects (NPRM)	Technical	The Environmental Education Act (P.L. 91-516, as amended by P.L. 93-278 and Title III, P.L. 95-561	Law provides general policy, implementing instructions are needed. Department has set a new policy which requires revision of regulations for purposes of simplification.	These regulations will describe the requirements for the award of grants for environmental education projects.	No	Sylvia Wright Program Officer Office of Environmental Education U.S. Office of Education FOB-6, Room 2025 400 Maryland Avenue, S.W. Washington, D.C. 20202 (202) 245-9231
Administration of Education Programs and Duties of the State Educational Agency (ESEA, Title V-A) (NPRM)	Policy Significant	Education Amendments of 1978	Law in general terms implementing instructions needed	This regulation will govern the program for consolidated administration of ESEA Titles I and IV	No	David G.Phillips Division of State Educational Assistance Programs, OE, 400 Maryland Ave.,SW, Washington, DC 20202, (202) 245-2495
Strengthening State Educational Agency Management (ESEA, Title V-B) (NPRM)	Policy Significant	Education AMendments of 1978	Law in general terms, implementing instructions needed	This regulation will govern a grant program to strengthen the leadership and management roles of SEAs	No	

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	*EA	CONTACT
Emergency School Aid (NPRM)	Policy Significant	The Education Amendments of 1978 (P.L. 95-561)	Law in general terms; implementing instructions needed	This regulation will clarify the status and establish program standards for issuing grant awards	No	L. Ann Benjamin Program Analyst Equal Education Opportunity Program Rm. 2011 400 Maryland Ave. S.W. Washington, D.C. (202) 245-8230
Special Assistance to State Education Agencies (NPRM)	Policy Significant	No Statute	No Law Program Authorized in FY 79 Budget request to Congress	These regulations will set out criteria for awarding SEA grants for FY '79	No	E. F. Jackson Program Analyst Equal Educational Program Rm. 2011 400 Maryland Ave S.W., Washington, D.C. 20202 (202) 245-8230
Programs for Children With Special Educational Needs (NPRM)	Policy Significant	Title I, Elementary and Secondary Education Act.	Some parts of law are general-others require regulations	These programs provide supplemental financial assistance to: (a) Local educational agencies for projects designed to meet the special educational needs of educationally deprived children in low-income areas; (b) State agencies to meet the special educational needs of handicapped, neglected or delinquent children; and (c) State Education Agencies to meet the special educational needs of migratory children.		Dr. John Staehle 400 Md. Ave., S.W (Room 3642 Rob3) Wash. D.C. 20202

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	*RA	CONTRACT
Follow Through (NPRM)	Policy Significant	The Economic Opportunity Amendments of 1978 (P.L. 95-568	The Department is considering major change in policy and is requesting public comment on proposal	This regulation will establish criteria for a second generation of Follow Through projects and sponsors.	No	Fred Bresnick Program Coordinator Division of Follow Through 400 Maryland Ave., S.W. (ROB#3 - Rm. 3624 Washington, D.C. 20202 (202) 245-2501

TITLE	CLASSIFICATION	BASE	REGULATE	DESCRIPTION	*RA	CONTACT
Biomedical Sciences (NPRM)	Policy Significant	Education Amendments of 1978 (P.L. 95-561)	Law in general terms implementing instructions needed	Program assist target youth to prepare and to pursue a course of study leading to one of the biomedical professions or occupations.	No	Simon McNeely Senior Program Coordination Officer/BESE/SLEP 400 Md. Ave.,SW Washington, D.C. 20202 (202) 245-8407
Health Education Program (NPRM)	Policy Significant	Education Amendments of 1978 (P.L. 95-561)	Law in general terms implementing instructions needed	The proposed regulations would govern the awarding of grants to State and local educational agencies which are designed to establish and support programs of health education in elementary and secondary schools	No	Simon McNeely Senior Program Coordination Officer/BESE/SLEP 400 Md. Ave.,SW Washington, D.C. 20202 (202) 245-8407

Assistance for Maintenance and Operation and School Construction in Areas Affected by Federal Activities (NPRM)	Policy Significant	Education Amendments of 1978 (P.L. 95-561)	Statute specifically requiring regulations; the statute sets general policy, major important implementing provisions need regulation; the Department has set new policies which require new or modified regulations.	The regulations govern reports, membership, average daily attendance, employment conditions of certain school personnel, nonpublic education of a handicapped child, children who live on Indian lands, elective school boards and payments in States that equalize expenditures among local educational agencies.	Mr. William L. Stormer Director, Division of School Assistance in Federally Affected Areas, Room 2107, 400 Maryland Ave., S.W Washington, D.C. 20202 Telephone (202) 245-8427

TITLE	CLASSIFICATION	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	ERA	CONTACT
Preschool Partnership Programs (NPRM)	Policy significant	Education Amendments of 1978	Law in general terms; implementing instructions needed	Regulations will establish requirements for participation in parent/early childhood pilot projects	No	Dr. Ernest A. Crider or Miss Beryl Parke Parent/Early Childhood and Special Programs Staff, DESE, OE Room 2083 400 Md. Avenue, S.W. Wash., D.C. 20202 202/245-8118
Population Education (NPRM)	Policy significant	Education Amendments of 1978	Law in general terms; implementing instructions needed	Regulations will establish requirements for participation in a program population education in elementary and secondary schools	No	As Above
Special Grants for Safe Schools (NPRM)	Policy Significant	ESEA Title IX, Part D, P.L. 89-10, as amended by The Education Amendments of 1978.	The Statute sets general policy, important implementing provisions need regulations.	The regulations will define terms, establish selection criteria, emphasize program direction, and limit amount of funds for equipment and remodeling.	No	Robert L.Thomas Education Program Specialist, Division of State Educational Assistance Program 400 Maryland, Ave. S.W. (Rm.3010, [illegible] Washington, D.C. 20202 (202)245-2605

	CLASSIFICATION	BASE	REGULATE	DESCRIPTION	*RA	CONTACT
Title I, ESEA Migrant (NPRM)	Policy Significant	Education Admendments of 1978 (P.L. 95-561)	Statute specifically requires Regulations	These regulations establish State and local advisory councils, adjust summer count of children, coordinate migrant education activities, reorder priority of services for currently pre-migratory children, establish a review procedure for State application standards, establish circumstances under which the Commissioner will bypass or reallocate a State's funds.	NO	John D. Ridgway Education Prog Specialist U.S. Office of Education 7th & D Streets, S.W. Washington, D.C. 20202

SOCIAL SECURITY ADMINISTRATION

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Reorganization and Updating of Reg. No. 1	Policy Significant	Privacy Act of 1974, (Pub. L. 93-579)	Strong public interest in SSA's rules on disclosing information from its records	Provides for disclosure of information from social security records under the Social Security Act, the Freedom of Information Act, the Privacy Act, and other related statutes.	No	Mr. Armand Esposito Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-5551
Totalization Agreements	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	Law in general terms, implementing instructions needed.	Implements a provision that authorizes the President to enter into bilateral agreements with other countries to provide for coordination between the social security system of the United States and other countries. Permits each country to establish entitlement to and amount of benefits based on a combination of a person's periods of coverage under social security systems of both countries.	No	Mr. John Mosler, Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7337
New Methods for Computing Benefit Amounts	Technical	Social Security Amendments of 1977 (Pub.L. 95-216)	Required to publish definition of "average of the total wages," and need for complex provisions to be explained in layman's language.	Explains the decoupling provisions of the Social Security Amendments of 1977 whereby a worker's basic benefit amount is computed from his earnings as a ratio of the total earnings of all workers. Explains the amended provisions for computing minimum benefit amounts and cost-of-living increases and recomputing the basic benefit.	No	Mr. Jack Schamberger Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-6785
Reduction of Benefits to Maximum	Technical	Social Security Amendments of 1977 (Pub. L. 95-216)	To complement regulations on "New Methods for Computing Benefit Amounts."	Provides a new formula for determining the maximum monthly benefit that a family can receive.	No	Mr. Jack Schamberger Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-6785

Title	Classification	Statutory Base	Need to Regulate	Description	PA	Content
Reduced Benefits for Spouses Receiving Government Pensions	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	To explain to the public a controversial provision of the Social Security Amendments of 1977.	Explains the pension offset provision whereby a spouse's social security benefit will be offset, or reduced by the amount of a public pension to which he or she is eligible. There is an exception—offset does not apply to spouses who are eligible for a public pension anytime before December 1982 and who meet the social security requirements that were in effect in January 1977 (i.e., an applicant for husband's or widower's benefits must have met a one-half support requirement).	No	Mr. Jack Schlesinger Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-6785
The Retirement Test; The Elimination of the Monthly Test, and the Age at Which the Retirement Test no Longer Applies	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	Law does not provide specificity for implementation	Implements a provision which permits payment of monthly benefits because of low earnings in a month only at the time of initial retirement. Thereafter, the right to payments depends on earnings in a year.	No	Ms. Clara [illegible] Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235
Effects of Annual Wage Reporting	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	The Social Security Amendments of 1977 require that we publish a definition of "the average of the total wages." This definition is used when we determine whether the amount of a person's income subject to social security taxes must be increased.	Reflects a change granting military wage credits for compensation other than cash. Changed from a monthly amount to an annual amount to conform to new annual reporting of wages.	No	Mr. Armen [illegible] Saito Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-[illegible]

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Recovery of Overpayments; Extension of Recovery Period	Technical	Secs. 204 and 205 of the Social Security Act.	Regulations prepared to preclude statutory emendment proposed by a Senator. Interim regulations published to alleviate public relations problem in State of Oregon	Liberalizes the period for recovery of an overpayment by removing the present 3-year time limitation in which overpayments must be recovered.	No	Mr. Marvel Cater Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7463
Reference Changes to Reflect Transfer and Recodification of Medicare Regulations	Technical	Secs. 205(a), 1102, and 1362 of the Social Security Act.	Cross references to be changed due to reorganization.	Modifying various references to 20 CFR Part 405 to reflect the redesignation of those regulations to 42 CFR Part 405 and which make the Health Care Financing Adm. rulings binding on all SSA components.	No	Mr. Phil Berra Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-59--7-52
State and Local Government Wage Reporting Requirements; Annual Basis	Policy Significant	An Act to amend the Social Security Act to expedite the holding of hearings under titles II, XVI, and XVIII by by establishing uniform review procedures under such titles, and for other purposes (Pub. L. 94-202)	This change will make all wage reports due annually. We currently have different schedules for private and State employers.	These regulations change the States' obligation for filing wage reports from one each quarter to one each year. This will reduce SSA's and the States' processing times.	No	Mr. Armand D'Ambrosio Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-59--5551
State and Local Coverage--Frequency with Which States Should Deposit Social Security Contributions	Policy Significant	Sec. 218(e) of the Social Security Act	This change to the deposit schedule will increase substantially the amount of interest income to the social security trust funds.	These regulations would require States to pay their FICA contributions 15 days after the end of each month rather than 45 days after each quarter. This speedup in collections will add millions of dollars per year to the trust funds.	No	Mr. Armand D'Ambrosio Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-59--5551

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Guidelines for Adjudicating Disability Claims in Which Vocational Factors Must Be Considered	Policy Significant	Secs. 205, 223, 1102, 1614, and 1631 of the Social Security Act, as amended	Consolidating and incorporating these policies into the regulations will serve to make clearer to claimants and their representatives how disability is determined where vocational factors must be considered.	Expand existing regulations to include additional detailed criteria for the evaluation of claims based on disability (under Titles II and XVI of the Social Security Act) in which a determination of disability cannot be made on medical severity alone or on the ability to do past work. Provides rules for evaluating age, education, and work experience in these kinds of disability claims.	No	Mr. William Ziegler Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7415
Disability Insurance Supplemental Security Programs Substantial Gainful Activity--Guidelines for 1978	Policy Significant	Secs. 223 and 1614 of the Social Security Act	The Social Security Act directs the Secretary to prescribed SGA criteria by regulations.	Increases the dollar amounts for determining whether a person's earnings show the ability to perform SGA for calendar years 1978 and 1979 and later.	No	Mr. James MacDonald Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7312
Revised Medical Criteria for the Determination of Disability	Policy Significant	Secs. 205(a), 1102, & 1614(a) of the Social Security Act.	Update present Listing to reflect medical advances and diagnosis and treatment that have occurred since last published Listing in 1968.	Revises the medical evaluation criteria currently used in the SSI and social security disability programs which describe the level of severity deemed sufficient to prevent a person from engaging in any gainful work activity. Recognizes medical advances both in treatment and in methods used to evaluate severity of particular impairments.	No	Mr. Harry [illegible] Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7455
Eligibility of Individuals Residing in Publicly Operated Community Residences Serving No More Than 16 Residents	Technical	Unemployment Compensation Amendments of 1976 (Pub. L. 94-566)	Rules are needed to define what is and what is not a publicly operated community residence serving 16 or fewer residents.	Provides that the term "public institution" does not include publicly operated community residences which serve no more than 16 residents. Also defines what are and are not publicly operated community residences which serve no more than 16 residents.	No	Mr. Sander [illegible]man Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7341

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Evidence of Permanent Residence in the United States Under Color of Law	Policy Significant	Sec. 1614(a)(1)(B) of the Social Security Act	To provide undocumented aliens another way to establish permanent residence in the United States under color of law.	Provides that aliens who have continuously resided in the United States since before January 1, 1970 will be presumed to be permanently residing in the United States under color of law for purposes of eligibility for SSI payment.	No	Mr. Sander Wiseman Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7341
Filing Date for Applications Based on Oral Inquiry	Policy Significant	Secs. 1102, 1611, and 1631 of the Social Security Act.	Under current regulations persons who make an oral inquiry about their eligibility for SSI benefits and are advised they are ineligible and therefore do not file an application cannot claim retroactive benefits if it is later found they were eligible. These regulations will protect such persons from losing benefits.	Specifies when the date of an oral inquiry is considered the filing date of an application for supplemental security income benefits.	No	Mr. Cliff Terry Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7919
Reductions of SSI Payments to Individuals in Substandard Institutions	Policy Significant	Unemployment Compensation Amendments of 1976 (Pub. L. 94-566)	Regulations will implement sec. 1616(a)(4) of the Social Security Act by setting forth method SSA will use for penalty reduction of SSI payments.	Prescribes the method of reducing SSI benefits payable to persons residing in facilities that do not meet approved State standards.	No	Ms. Virginia Mahan Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-6629

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Amount of Benefits; Computation of Certain Benefits Under Title XVI; Essential Persons	Technical	Unemployment Compensation Amendments of 1976 (Pub. L. 94-566)	Secretarial decision to delete from regulations all benefit amounts which previously reflected cost-of-living increases.	Deletes tables of increased benefit amounts from existing regulations. Reference is made to basic statutes and to notices in the Federal Register to ascertain current benefit amounts.	No	Mr. Marval Cozer Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7463
Unearned Income, One-Third Reduction for Living in Another Person's Household	Policy Significant	Sec. 1612 of the Social Security Act.	Rules are needed to describe when the one-third reduction applies and when it does not apply.	Provides that the standard payment amount for an eligible individual (or couple) who lives in another person's household and receives support and maintenance from such person will be reduced by one-third. The actual value of such support and maintenance is not established.	No	Mr. Sanier Waisman Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7341
Medical and Social Services Which Are Not Income	Policy Significant	Sec. 1612 of the Social Security Act	To fulfill sec. 1612(b)(6) of the Social Security Act.	Excludes from the SSI definition of income certain medical and social services. This means those furnished in conjunction with any governmental or nongovernmental assistance program based on need.	No	Mr. Henry Lerner Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7-1-
Exception to the One-Third Reduction Provision and Income and Resources Exclusion When An Individual is Affected by a Major Disaster	Policy Significant	Major Disasters Presidentially declared. (Pub. L. 94-331, Pub. L. 94-955, and Pub. L. 95-171)	Required by statute to be reflected in regulations.	Provides additional exclusions in determining countable income and resources for payments of SSI benefits when an individual is affected by a Presidentially declared major disaster.	No	Mr. Henry Lerner Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7-1-
Replacement of Damaged or Lost Excluded Resources	Policy Significant	Sec. 1613 of the Social Security Act	These regulations apply to non-Presidentially declared disasters and parallel the major disaster statutes.	Excludes from income and resources, assistance received from any source for the repair or replacement of certain damaged, lost, or stolen property.	No	Mr. Henry Lerner Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7-1-

6

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Exclusion from Resources of the Property Essential to Self Support	Policy Significant	Social Security Amendments of 1972 (Pub. L. 92-603) and Internal Revenue Code of 1954--Distilled Spirits Stamp (Pub. L. 94-569)	Current regulations merely provide that property essential to self-support shall be excluded from resources but do not provide value limitations. These regulations provide the necessary guidelines.	Provides guidelines for determining property essential to self-support is excluded from countable resources under the SSI program. Also provides that even if income-producing property is associated with the home, the home (including land appertaining to it and buildings on the land) is excluded as a resource regardless of its value or use.	No	Mr. John [illegible] Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7337
Evaluating Resources on the Basis of Equity and Increasing Dollar Limit on Certain Excluded Resources	Policy Significant	Sec. 1613 of the Social Security Act	Secretarial decision to regulate.	Increases the reasonable value of household goods and personal effects from $1,500 to $2,000 and the value of an automobile from $1,200 to $2,000. Values within these amounts will not affect eligibility for SSI payments. Also provides for evaluating resources on the basis of equity in the resource rather than its current market value.	No	Mr. Henry Lerner Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7[illegible]
Permitting Individuals Applying for or Receiving SSI to File for Food Stamps in Social Security Offices	Policy Significant	Food and Agriculture Act of 1977 (Pub. L. 95-113)	Food and Agriculture Act of 1977 is in general terms. SSA needs regulations for instructions	Describes SSA's authority (with the concurrence of the Department of Agriculture) to obtain information from individuals solely for food stamp purposes.	No	Ms. Dorothy [illegible] Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-[illegible]
Pass Along Provisions of Federal Supplemental Security Income Benefit Cost-of-Living Increases to State Supplementary Recipients with Limitation on State Cost for Hold-Harmless States	Policy Significant	Food Stamp Distribution to AFDC Families (Pub. L. 94-585)	Law is not specific enough to be entirely self-effectuating.	Implement provisions of sec. 1618 of the Social Security Act by interpreting the statute to include those beneficiaries who receive only State supplementation and to provide guidelines for related State agreements.	No	Ms. Clara [illegible] Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7-[illegible]

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Social Security Number Issuances	Policy Significant	Social Security Amendments of 1972 (Pub. L. 92-603)	These regulations are necessary to protect the integrity of the social security number by exercising all means available to SSA to curtail the abuse and misuse of the social security number.	Requires that all applicants for social security numbers submit documentary evidence of identity, age, and citizenship or alien status. Also requires that all applicants for duplicate social security number cards submit sufficient evidence to establish their identity.	No	Mr. Phil Berre Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7452
Quality Control System; Incentive Adjustment for Quality Control in Federal Financial Participation in the AFDC Program	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	To provide methods for calculating payments to States; to improve quality control system.	Provides for incentive payments to States for reducing their AFDC error rate below 4 percent.	No	Mr. Sean Hurley Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-[illegible]
Aid to Families with Dependent Children; Fiscal Disallowance for Erroneous Payments	Policy Significant	Sec. 403 of the Social Security Act	Policies will affect all States and must be published in regulations in order to be binding.	Provides States administering AFDC programs with a fiscal incentive for reducing AFDC quality control error rates.	No	Mr. Sean Hurley Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-[illegible]
Standards of Personnel Administration (AFDC)	Policy Significant	Sec. 403 of the Social Security Act	To provide personnel standards that States must abide by.	Revise and recodify policies related to financial assistance programs provided under the Social Security Act. It is necessary to recodify those now administered by SSA, formerly administered by the now defunct SRS.	No	Miss [illegible] Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-[illegible]

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Disregard of Income Earned by Youth (AFDC)	Technical	Youth Employment and Demonstration Act of 1977 (Pub. L. 95-93)	Rules are needed to exclude income provided by this statute.	Beginning August 5, 1977, earnings received by a youth under Part C of the Comprehensive Employment Act of 1973, shall be disregarded in determining the family's eligibility for, and amount of, any benefit based on need and funded by Federal or federally assisted programs.	No	Mrs. Juanita Henderson Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-0203
Protective, Vendor, and Two-Party Payments for Dependents (AFDC)	Policy Significant	An Act to extend certain Social Security Act provisions and for other purposes (Pub. L. 95-171)	To implement sec. 3 of Pub. L. 95-171 which increases from 10% to 20% the Federal matching funds available to States for the number of individuals for whom protective, vendor, and two-party payments can be made in any month.	Increases from 10 to 20 percent the Federal matching of funds for protective and two-party payments in State AFDC cases. Two-party payment checks require endorsement by the individual and the provider of care.	No	Mr. Clifford Wooldridge Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-0017
Section 1115(b) Demonstration Projects	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	Regulations will provide policy information needed by States in developing projects and will inform AFDC recipients and the organizations that represent them of requirements to be met by States and Federal government.	Provide necessary details, instructions, and policy for State implementation of experimental pilot and demonstration projects, administered by SSA. The purpose is to improve methods and techniques of providing AFDC payments and to promote work incentive.	No	Ms. Virginia Cohen Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-[illegible]

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Need and Amount of Assistance; Methods for Budgeting Income (AFDC)	Policy Significant	Sec. 402 of the Social Security Act, as amended	To clarify policies for States to measure income of financial assistance applicants.	Provide a clarification of the budgeting methods which States may use in determining financial eligibility for AFDC payments.	No	Mrs. Constance Katz Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-0[illegible]
Factors Specific to AFDC Continued Absence of Parent-Prisoner	Policy Significant	Secretarial commitment made to Senator Eastland	To revise policy so that certain families can receive AFDC payments.	Where parent-prisoner returns home in evenings, and does uncompensated public work by day, child is deprived of support for AFDC purposes.	No	Miss Joyce Fernandez Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-0[illegible]
Access to Wage Record Information Under AFDC	Policy Significant	Social Security Amendments of 1977 (Pub. L. 95-216)	These rules state specific requirements to be met by the States in requesting and using wage information.	States must request and use wage information from State unemployment compensation agency or SSA at specified periods; must maintain certain automated files; must maintain certain safeguards; must maintain statistical records.	No	Miss Helen Hamilton Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-167[illegible]
Old-Age, Disability Dependents' and Survivors' Insurance Benefits	Policy Significant	Secs. 202, 205, 216, and 223 of the Social Security Act	Incorporates pertinent provisions of P.L. 95-216 and recent court decisions affecting interpretation of certain provisions of the Act.	Describes the requirements for becoming entitled to benefits under Title II of the Act.	No	Mr. Ray Worley Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-57[illegible]
Filing Date of Applications and Other Forms	Technical	Secs. 205 and 1102 of the Social Security Act	To provide public with clearer regulations and to implement sec. 332 of the Social Security Amendments of 1977.	Recodifies SSA's requirements for filing applications for RSDHI and SSI benefits.	No	Mr. James MacDonald Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7310

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Maintenance and Revision of Records of Wages and Self-Employment Income	Technical	Secs. 205 and 1112 of the Social Security Act	To provide public with clearer regulations.	Recodifies SSA's rules on earnings records.	No	Mr. James MacDonald Office of Policy and Regulations 6401 Security Blvd. Baltimore, MD. 21235 301-594-7316
Employment-Wages-Self-Employment Income	Technical	Title II of the Social Security Act, as amended.	This subpart is being rewritten under "Operation Common Sense."	This regulation will, in simpler terms, define the types of work that are included or excluded for social security purposes.	No	Mr. Dave Smith Office of Policy and Regulations 6401 Security Blvd. Baltimore, MD. 21235 301-594-7951
Rights and Benefits Based on Disability and Determination of Disability or Blindness	Policy Significant	Secs. 205, 223, 1102, 1614, and 1631 of the Social Security as amended.	These regulations are being rewritten to meet the Department's "Operation Common Sense" standards.	These regulations include the rules for determining disability under Title II and determining disability and blindness under Title XVI of the Social Security Act. These regulations are being rewritten to make them clearer and easier to understand, to remove provisions that are obsolete and rarely applicable, and to examine the policies and consider additions, revisions, and clarifications.	No	Mr. William Ziegler Office of Policy and Regulations 6401 Security Blvd. Baltimore, MD. 21235 301-594-7415
Procedures, Payments of Benefits, Determinations, Appeals, and Representation of Parties	Policy Significant	Secs. 205,1102 and 1631 of the Social Security Act	These subparts are being rewritten under "Operation Common Sense."	Explains the administrative review process and procedures relating to claimant representation.	No	Mr. Phil Berge Office of Policy and Regulations 6401 Security Blvd. Baltimore, MD. 21235 301-594-7452

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Income and Exclusions; Supplemental Security Income Program	Policy Significant	Sec. 1612 of the Social Security Act.	To provide the public with clearer regulations.	Explains how we consider income under the supplemental security income program and the amount of individual benefits.	No	Mr. Sander Waisman Office of Policy and Regulations 6401 Security Blvd. Baltimore, Md. 21235 301-594-7341
Financial Assistance Programs	Policy Significant	Titles I, IV-A X, XIV, and XVI (AABD) of the Social Security Act	Simplify and reorganize current regulations to reflect 1977 HEW reorganization and related delegations of authority.	Will combine into one Part existing general rules and procedures on administration of financial assistance programs.	No	Mr. Larry Love Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-0958
Date When Assistance Begins	Policy Significant	Sec. 206.10(a)(6) of the Social Security Act	The regulation will bring about consistency and increase uniformity among States and equality for applicants because entitlement to assistance will begin at the same time regardless of residence.	This regulation provides that the date of entitlement of assistance must be the first of the month in which the application is received.	No	Miss Alice Stewart Office of Family Assistance Rm. 4111 Switzer Bldg. 330 C Street, S.W. Washington, D.C. 20201 202-245-1694

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Title	Type	Classification	Statutory Base	Need to Regulate	Description	RA 1/	Contact
Grants for Community Mental Health Centers	F	Policy Significant	P.L. 94-63 P.L. 95-83	Required by statute	Establish requirements for grants & applications for grants under the CMHC Act. It includes requirements for the development, submission, and approval of State plans.	No	Lindsley Williams OPDA/NIMH 5600 Fishers Lane Rockville, Md. (301) 443-3175
Formula Grants for Drug Abuse Prevention Functions	F	Policy Significant	P.L. 92-255 Section 409	Required by statute	Authorizes formula grants to States to assist them in the preparation & admin. of plans for planning, establishing, conducting, & coordinating projects for the development of more effective drug abuse prevention functions in carrying out projects under and otherwise implementing the plans; and in evaluating the results of implementation plans.	No	Nancy Soulen OD/NIDA 5600 Fishers Lane Rockville, Md. (301) 443-1644
Grants to States for Alcohol Abuse & Alcoholism Prevention, Treatment & Rehabilitation Services & National Alcohol Research Centers (Interdisciplinary research grants)	IF	Policy Significant	P.L. 95-26 & P.L. 94-371	Required by statute	Authorizes the designation of National Alcohol Research Centers for the purpose of long-term interdisciplinary research into alcoholism & other alcohol problems and to make grants to such Centers (not to exceed $1,000,000 to any one Center in a year).	No	Susan Farrell Legislative Services NIAAA 5600 Fishers Lane Rockville, Md. (301) 443-4375

Grants to States for Alcohol Abuse and Alcoholism Prevention, Treatment, & Rehabilitation Services & National Alcohol Research Centers (Grants for Uniform Alcoholism & Intoxication)	NPRM	Policy Significant	P.L. 94-371 Section 310	Required by statute	Authorizes special grants to States which have adopted the basic provisions of the Uniform Alcoholism & Intoxication Treatment Act. The Uniform Act requires that alcoholism be viewed as an illness to be treated by community health & social service agencies and that public intoxication be approached as a public health problem rather than a crime.	No Susan Farrell Legislative Servic NIAAA 5600 Fishers Lane Rockville, Md. (301) 443-4375

Center for Disease Control

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Specifications for Medical Examinations of Underground Coal Miners -- Amendments to Transfer Criteria (42 CFR Part 37)(Final)	Technical	Sec. 203 of the Federal Coal Mine Health and Safety Act, as amended by the Federal Mine Safety and Health Act of 1977	To implement new policies on transfer criteria.	Revises the medical conditions under which coal miners will be allowed to transfer to less dusty areas of coal mines.	No	Mr. Harlan Amandus, Chief, Examination Processing Branch, Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, Center for Disease Control, 944 Chestnut Ridge Rd. Morgantown, West Va. 26505, 304-923-7306.
Grants for Advancement of Health in Coal Mining (42 CFR Part 55); Requests for Health Hazard Evaluations (42 CFR Part 85); and Occupational Safety and Health Investigations of Places of Employment (42 CFR Part 85a)(NPRM)	Technical	Federal Mine Safety and Health Act of 1977	To implement changes in NIOSH research responsibilities under the Federal Mine Safety and Health Act of 1977.	Amends existing regulations to reflect research responsibilities given to the National Institute for Occupational Safety and Health, Center for Disease Control, under the Federal Mine Safety and Health Act of 1977.	No	Ms. Mary Flint Regulations Specialist, National Institute for Safety and Health, Center for Disease Control, 5600 Fishers Lane, Room 8-11, Rockville, Md. 301-443-3745.
Respiratory Protective Devices -- Use of Approved Devices (30 CFR Part 11)(Final)	Technical	Secs. 202 and 204 of the Federal Coal Mine Health and Safety Act, as amended by the Federal Mine Safety and Health Act of 1977	To establish an extended use date for respirators resulting from policy changes.	Extends the period during which use of certain self-contained breathing apparatus approved under the former Bureau of Mines approval program is allowed.	No	Mr. Robert Schutz, Chief, Testing and Certification Branch, Division of Safety Research, National Institute for Occupational Safety and Health, Center for Disease Control, 944 Chestnut Ridge Rd., Morgantown, W. Va. 26505, 304-923-7331.

Title	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Grants for Disease Control (42 CFR Part 51b)(Final)	Technical	Secs. 317 and 318 of the Public Health Service Act	To implement changes made by several public laws enacted since existing regulation was issued.	Revises requirements for grants to State and local government agencies to assist them in meeting costs of disease control programs.	No	Dr. J. Donald Millar, Director, Bureau of State Services, Center for Disease Control, Atlanta, Ga. 30333, 404-329-3771, or FTS: 236-3771
Grants for the Prevention of Lead-Based Paint Poisoning (42 CFR Part 91) (Final)	Technical	Secs. 101, 504, and 505 of the Lead-Based Paint Poisoning Prevention Act	To implement changes made by several public laws which amended the Lead-Based Paint Poisoning Prevention Act.	Revises requirements for grants to support programs in prevention of lead-based paint poisoning in children.	No	Dr. Vernon N. Houk, Director, Environmental Health Services Division, Center for Disease Control, Atlanta, Ga. 30333, 404-262-6645 or FTS: 236-6645
Disinsecting of Aircraft (42 CFR Part 71) (NPRM)	Technical	Sec. 361 of the Public Health Service Act	To implement improved procedural changes for disinsecting aircraft.	Eliminates the requirement for routine disinsecting of aircraft on certain international flights landing at airports under U.S. control.	No	Mr. Joseph F. Giordano, Director, Quarantine Division, Bureau of Epidemiology, Center for Disease Control, Atlanta, Ga. 30333, 404-326-3674, or FTS: 236-3674

Title	Type	Classification	Statutory Base	Need to Regulate	Description	RA 1/	Contact
Designation of Health Manpower Shortage Areas	F	Policy Significant	P.L. 94-484 Section 332(b)	Required by statute	To establish criteria for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health manpower shortage areas	No	Richard Lee Bureau of Health Manpower, HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 2078 (301) 436-6764
Programs for the Training of Physician Assistants	F	Policy Significant	P.L. 94-484 Section 701(7)	Required by statute	To prescribe requirements for programs for the training of physician assistants	No	Kenneth Moritsugu Bureau of Health Manpower, HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6424
Grants for Physician Assistant Training Programs	F	Policy Significant	P.L. 94-484 Section 783	Required by statute	To govern grants to public or nonprofit private schools of medicine and osteopathy and other public or nonprofit private entities for projects to plan, develop, and operate or maintain programs for the training of physician assistants	No	Kenneth Moritsugu Bureau of Health Manpower, HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6424
Programs for the Training of Expanded Function Dental Auxiliaries	F	Policy Significant	P.L. 94-484 Section 701(8)(b)	Required by statute	To prescribe requirements for programs for the training of expanded function dental auxiliaries	No	Richard Weaver Bureau of Health Manpower, HRA Center Building 3700 East-West Hwy Hyattsville, Md. 20782 (301) 436-6510

1/ RA - Regulatory Analysis

Grants for Programs for the Training of Expanded Function Dental Auxiliaries	F	Policy Significant	P.L. 94-484 Section 783(a)(2)	Required by statute	To govern grants to schools of dentistry and other public or nonprofit private entities for projects to plan, develop and operate or maintain programs to train dental students in the organization and management of multiple auxiliary dental team practice	No	Richard Weaver Bureau of Health Manpower, HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6510
Criteria for Payment of Tuition and other Educational Costs	F	Policy Significant	P.L. 94-484 Section 711	Required by statute	To establish criteria to be used in determining allowable increases in tuition and other educational costs for which the Secretary is responsible under the National Health Service Corps Scholarship Program, the Indial Health Scholarship Program, and Scholarships for First-Year Students of Exceptional Financial Need	No	Donald C. Parks Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6560
Health Professions Student Loans	F	Policy Significant	P.L. 94-484 Section 740-744	Required by statute	To implement requirement for health professions schools to be eligible to participate in the health professions student loan program and for individuals to receive repayment of their eligible loans for service in designated health manpower shortage areas.	No	John Belin Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6310
Traineeships for Students in Schools of Public Health & Other Graduate Public Health Programs	F	Policy Significant	P.L. 94-484 Section 748	Required by statute	To set forth requirements for implementing the Secretary's authority to award grants to schools of public health or nonprofit private educational entities to support traineeships for students in the graudate education programs of these entities in public health	No	Merrill DeLong Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6824

Traineeships for Students in Graduate Programs in Health Administration; Hospital Administration or Health Policy Analysis and Planning at Public or Nonprofit Private Educational Institutions Other than Schools of Public Health	F	Policy Significant	P.L. 94-484 Section 749	Required by statute	To set forth requirements for implementing the Secretary's authority to make grants to public or nonprofit private educational entities (excluding schools of public health) to support traineeships in graduate educational programs of such entities in health admin. hospital admin., or health policy analysis and planning.	No	Merrill DeLong Bureau of Health Manpower Center Building 3700 East-West Hwy. Hyattsville, Md. 2078 (301) 436-6824
National Health Service Corps Scholarships	F	Policy Significant	P.L. 94-484 Section 751	Required by statute	The regs are applicable to the award of scholarships under the National Health Service Corps Scholarships Program to students receiving academic training in medicine, osteopathy, dentistry, and other health professions in order to assure an adequate supply of trained health professions to improve the delivery of health services in health manpower shortage areas	No	Gary Wold Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 2078
Scholarships for First-Year Students of Exceptional Financial Need	F	Policy Significant	P.L. 94-484 Section 758	Required by statute	The regulations given the award of grants to health professions schools to provide scholarships for full-time first-year students of exceptional need	No	John Belin Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6310

Health Professions Capitation Grants	IF	Policy Significant	P.L. 94-484 Section 770-772	Required by statute	The regs implement the award of annual grants to schools of medicine, osteopathy, dentistry, public health, veterinary medicine, optometry, pharmacy, and podiatry for the support of the education programs of those schools	No	John Westcott Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6564
Special Assurances Required of Schools of Medicine Applying for Health Professions Capitation Grants	F	Policy Significant	P.L. 94-484 Section 771(b)(3)	Required by statute	The regs implement certain requirements for schools of medicine to be eligible for capitation grants	No	Dr. Robert Knouss Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6424
Area Health Education Centers	F	Policy Significant	P.L. 94-484 Section 781	Required by Statute	The regs are to establish standards & criteria for the award of contracts and the implementation of the programs The purpose of these programs are: to improve the distribution, supply quality, utilization, and efficiency of health personnel in the health services delivery system and to encourage the regionalization of educational responsibilities of health professions schools	No	Dr. Robert Knouss Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6418
Grants for Dental Team Practice	F	Policy Significant	p.L. 94-484 Section 783(a)(3)	Required by statute	These regs give grants to schools of dentistry and other public or nonprofit private entities for projects to plan, develop, and operate and maintain programs to train dental students in the organization & management of multiple auxiliary dental team practice	No	Richard Weaver Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6510

Grants for Residency Training in General Internal Medicine or General Pediatrics	F	Policy Significant	P.L. 94-484 Section 784	Required by statute	The regs define requirements for grants for residency programs in general internal medicine or general pediatrics	No	Kenneth Moritsugu Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6424
Grants for Training in Family Medicine	F	Policy Significant	P.L. 94-484 Section 786(a)	Required by statute	The regs assure guidelines for grants to assure the institutionalization of family medicine within the schools of medicine & osteopathy, to encourage students, through the context of educational programs and through the contact with role model family physician and to pursue careers in family medicine	No	Dr. Robert Knouss Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6418
Educational Assistance to Individuals from Disadvantaged Backgrounds	F	Policy Significant	P.L. 94-484	Required by statute Sections 787 & 798	To govern grants to provide educational assistance to individuals from disadvantaged backgrounds to undertake training and education to enter the health professions or allied health professions	No	Kinzo Yamamoto Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20783 (301) 436-7230
Grants to Schools of Medicine, Dentistry, Public Health, Osteopathy Optometry, Podiatry, Pharmacy and Veterinary Medicine for Start-Up Assistance	NPRM	Policy Significant	P.L. 94-484 Section 788(a)	Required by statute	To set forth procedures for awarding grants authorized by the Health Professions Educa. Assistance Act of 1976. Specif. grants to provide start-up assistance for initiating new schools of medicine, osteopathy, dentistry, public health, veterinary medicine, optometry, pharmacy & podiatry	No	John Westcott Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6564

HEALTH RESOURCES ADMINISTRATION
Health Manpower

Health Professions Financial Distress Grants	IF	Policy Significant	P.L. 94-484 Section 788(b)	Required by statute	To implement the awarding of grants to assist schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, podiatry, pharmacy and public health in meeting their costs of operation, if they are in serious financial distress, or in meeting accreditation requirements, if they have a special need for assistance in meeting these requirements, & to carry out appropriate operational, managerial, and financial reforms	No	Donald C. Parks Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6560
Grants for Training in Emergency Medical Services	F	Policy Significant	P.L. 94-484 Section 789	Required by statute	To set forth requirements for grants for training programs in emergency medical services	No	Daniel Mosica Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6424
Grants for Graduate Programs in Health Administration	F	Policy Significant	P.L. 94-484 Section 791	Required by statute	To implement the Sec.'s authority to make grants to public or nonprofit private educational entities (excluding schools of public health) to support the health admin. and health planning graduate educational programs of such entities	No	Merrill DeLong Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6824

Grants to Develop New Graduate Programs or Expand Existing Programs in Public Health	F	Policy Significant	P.L. 94-484 Section 792	Required by statute	To implement the Sec's authority to make grants to schools of public health & other public or non-profit educational entities for projects to develop new graduate programs or to expand existing programs in biostatistics, epidemiology, health admin., health planning, health policy analysis & planning environmental or occupational health and dietetics & nutrition.	No	Merrill DeLong Bureau of Health Manpower/HRA Center Building 3700 East West Hwy. Hyattsville, Md. 20782 (301) 436-6824
Allied Health Special Project Grants & Contracts	NPRM	Policy Significant	P.L. 94-484 Section 796	Required by statute	To implement the Sec's authority to make grants to a. establish regional or State systems to assure that allied health and nursing personnel needs in the area are met by coordinating & managing allied health & nursing education & training among educational institutions; b. establish or improve recruitment, training and retraining programs for allied health personnel, and c. establish career ladders & advancement programs for practicing allied health personnel.	No	Merrill DeLong Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6824
Traineeships for Advanced Training of Allied Health Personnel	F	Policy Significant	P.L. 94-484 Section 797	Required by statute	To set forth requirements for grants to public or private non-profit institutions to meet the costs of traineeships for the advanced training of allied health personnel to a. teach in allied health training programs, or b. serve in administrative or supervisory capacities.	No	Merrill DeLong Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6824

Capitation Grants to Schools of Nursing	F	Policy Significant	P.L. 93-641 Section 810	Required by statute	To set forth requirements for annual capitation grants to schools of nursing for support of their educational programs	NO	Dr. Mary Hill Bureau of Center Building 3700 East-West Hwy. Hyattsville, Md. 2078: (301) 436-6681
Grants for Nurse Practitioner Traineeship Programs	NPRM	Policy Significant	P.L. 93-64 Section 830	Required by statute	To set forth requirements for grants to schools of nursing medicine, and public health, public or nonprofit private hospitals, and other nonprofit entities to meet the costs of traineeships for the training of nurses who reside in health manpower shortage areas and who sign a commitment to practice in health manpower shortage areas having shortages of primary medical care manpower	No	Dr. Mary Hill Bureau Center Building 3700 East-West Hwy. Hyattsville, Md. 2078: (301) 436-6681
Grants for Traineeships for Advanced Training of of Professional Nurses'	NPRM	Policy Significant	P.L. 93-64 Section 830	Required by statute	To govern the award of grants to public and non-profit institutions to cover the costs of traineeships for the advanced training of professional nurses	No	Dr. Mary Hill Bureau Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6681
Interdisciplinary Team Training & Curriculum Development for Health Manpower Training		Technical	P.L. 94-484 Health Professions Educational Assistance Act	Statute specifically requires regulation	To establish requirements for grants for interdisciplinary team training among schools in various health disciplines and for curruculum development in various areas related to health manpower.	No	Peggy Washburn Bureau of Health Manpower/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-7458

Title	Type	Classification	Statutory Base	Need to Regulate	Description	RA 1/	Contact
State Medical Facilities Plan #632	NPRM	Policy Significant	National Health Planning Act & Resources Development Act of 1974 P.L. 93-641	Statute spec requires regs by 1603(a) of PHS Act, Title XVI of the Act	To provide assistance, through grants, loans & loan guarantees with interest subsidies for projects for the 1. modernization of medical facilities; 2. construction of new outpatient medical facilities; 3. instruction of new outpatient medical facilities in areas which have experienced recent rapid population growth and 4. conversion of existing medical facilities to provide new health services	No	Robert Soliz Bureau of Health Planning & Resources Development, HRA Center Bldg 3700 East-West Hwy Hyattsville, Md. 20782 (301) 436-6870
National Guidelines for Health Planning	NPRM	Policy Significant	National Health Planning & Resource Development Act P.L. 93-641	Statute spec requires reg Sec. 1501 of PHS Act	The guidelines co of National Health Planning goals with respect to health status, health promotion, & disease prevention, and access to services	No	Office of Assistant Administrator on Planning, Evaluation & Legislation, HRA Center Building Room 10-22 3700 East-West Hwy Hyattsville, Md. 20782 (301) 436-7270

1/ RA - Regulatory analysis

Requirements for Provision of Services to Persons Unable to Pay Therefor and Community Service By Assisted Health Care Facilities	NPRM	Policy Significant	Titles VI & XVI of PHS Act	Statute specs require reg	Establishes requirements for health care facilities assisted by DHEW under Title VI & XVI of PHS Act to fulfill certain assurances that they give in their applications for assistance	No	Colin C. Rorrie, Jr. Ph.D Acting Director Bureau of Health Planning & Resources Development/HRA Center Building 3700 East-West Hwy Hyattsville, Md. 20782 (301) 436-6850
Loans & Loan Guarantees for Medical Facility Construction and Modernization	NPRM	Policy Significant	National Health Planning & Resources Development Act of 1974 P.L. 93-641	Statute spec requires reg	To provide direct loans to public or private non-profit entities and to guarantee loans made by non-Federal lenders to nonprofit private entities. The loans may be used to modernize medical facilities, construct new out-patient medical facilities, construct new inpatient medical facilities in areas which have expanded rapid population growth or convert existing medical facilities for the provision of new health services.	No	Colin C. Rorrie, Jr. Ph.D Acting Director Bureau of Health Planning & Resources Development/HRA Center Building 3700 East-West Hwy. Hyattsville, Md. 20782 (301) 436-6850

Health Services Administration

	Title	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
(F)	MCH Referral & Svcs for Blind & Disabled Children receiving SSI Benefits	Technical	Sec. 1615(b) SSA	Implementation Provisions Needed	Regs will provide requirements for services to and referral of blind and disabled children who are SSI beneficiaries and are referred by the Social Security Adm.	No	James J. Corrigan Director, Division of Policy Development, BCHS Rm. 6-17, Parklawn Bldg. 5600 Fishers Lane Rockville, MD 20857
(N)	Amendments to MCH-CC Svcs Programs Regulations	"	Title V SSA	"	Regs will implement statutory amendments dealing with reasonable costs and will make clarifying administrative changes	"	"
(F)	Projects for training home health personnel	"	Sec. 339(b) PHS Act, P.L. 95-626	"	Regs will provide requirements for projects to train personnel of home health agencies to assure high quality of care	"	"
(F)	Project grants for family planning svcs	"	Title X, PHS Act amended by P.L. 95-613	"	Regs will make changes required by P.L. 95-613 adding infertility svcs and svcs for adolescents	"	"

*RA = Regulatory Analysis (Yes/No)

	Title	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
(N)	Health & Nutrition Demonstration Projects/Dept. of Commerce	Technical	Sec. 516 of the Regional Development Act of 1975	Implementation Provisions Needed	Regs will establish requirements for multi-county health & nutrition demonstration projects in economic development regions	No	James J. Corrigan Director, Division of Policy Development, BCHS Rm. 6-17, Parklawn Bldg. 5600 Fishers Lane Rockville, MD. 20857
(F)	Assignment of NHSC Personnel	"	Sec. 333, PHS Act	"	Regs will establish requirements for assignment of NHSC personnel to health manpower shortage areas	"	"
(F)	Genetic Disease Testing and Counseling Services	"	Title XI of the PHS Act	"	Regs will establish requirements for grants to plan, establish and operate genetic disease testing and counseling programs	"	"

*RA = Regulatory Analysis (Yes/No)

National Institutes of Health

	TITLE	CLASSIFIC.	STATUTORY BASE	NEED TO REGULATE	DESCRIPTION	RA	CONTACT
N	Proposed PHS Regs. for NIH, NIAMDD--Grants for Comprehensive Centers	Policy Significant	Nat'l. Arthritis Act of 1974 (P.L. 93-640) Nat'l. Diabetes Mellitus Research & Educ. Act (P.L. 93-354) Arthritis, Diabetes, & Digestive Diseases Amend. of 1976 (P.L. 94-562)	The statute sets general policy, major important implementing provisions need regulation.	This reg. covers grants by NIAMDD for the support of (1)comprehensive centers for research, training, & info. dissemination concerning diabetes & (2) comprehensive centers for research, training, & info. dissemination concerning arthritis.	No	[Arthritis] Dr.Hausman, Spec. Asst. to Assoc. Dir., NIAMDD, NIH, Westwood Bldg., Rm. 403, Bethesda, Md. (301) 496-7495 [Diabetes] Dr. Krueger, Spec. Diabetes Prog. Dir., NIAMDD, NIH, Westwood Bldg., Rm. 622, Bethesda, Md. (301) 496-7418
F	Protection of Human Subjects--Regs. on Research Involving Children	Policy Significant	Nat'l Research Act (P.L. 93-348)	Statute specifically requires appropriate admin. action by Sec. Sec. has decided to issue regs.	Regs. provide additional protections for subjects of DHEW conducted or supported research involving children	No	Dr. Duncan OPRR, NIH, Westwood Bldg., Rm. 304, Bethesda, Md. (301) 496-7005
N	Protection of Human Subjects - Compensation of Human Subjects Injured in DHEW Supported Biomedical & Behavioral Research	Policy Significant	Not specifically required by legis., general authority PHS Act Section 301	The Dept. is considering major changes in policy & is requesting public comment on proposal	Regs. would require instit. applying for DHEW grants or contracts in support of research involving human subjects to provide assurances that they have in force mechanisms to provide compensation for indiv. who suffer injury as a result of their participation as subjects.	No	Dr.McCarthy, Dir. OPRR, NIH, Westwood Bldg. Room 304, Bethesda, Md. (301) 496-7005

ITEM	CHARACTER.	BASE	DESCRIPTION	EA	CONTACT
N Protection of Human Subjects - Regs. on Research Involving Those Instit. as Mentally Disabled	Policy Significant	Natl. Research Act (P.L. 93-348)	Statute specifically requires appropriate admin. action by Sec. The Sec. has decided to issue regs.	Dept. provide additional protections for subjects of DHEW conducted or supported research involving those instit. as mentally disabled.	NO	Dr. Marches, OPRR, NIH; Westwood Bldg, Rm. 304, Bethesda, Md. (031) 496-7005

Office of Health Maintenance Organizations

	Title	Classification	Statutory Base	Need to Regulate	Description	RA[1/]	Contact
F	Subpart A - Requirements for a Health Maintenance Organization	Policy Significant	Title XIII of the Public Health Service Act, as amended	Law requires the development of regulations	Defines the health benefits, providers of health services, method of payment, organization and operation of the HMO, and special requirements with respect to titles XVIII & XIX members.	No	H.Earle Belue Regulations Office, OHMO, Park Building, Room 3-32, 12420 Parklawn Drive, Rockville, Md. 20857 301-443-4695
F	Subpart B - Federal Financial Assistance: General	do	do	do	Sets forth requirements for the award of grants, loans & loan guarantees to public or nonprofit private entities or private entities (other than nonprofit private entities) for feasibility surveys, planning and initial development costs, and initial operation costs.	No	do

1/ RA - Regulatory analysis (Yes/No)

	Title	Classification	Statutory Base	Need to Regulate	Description	RA[1/]	Contact
N	Subpart C - Grants for Feasibility Surveys	Policy Significant	Title XIII of the Public Health Service Act, as amended	Law requires the development of regulations	Sets forth requirements for conducting surveys to determine the feasibility of developing and operating or expanding the operation of HMOs.	No	H.Earle Belue Regulations Office, OHMO, Park Building, Room 3-32, 12420 Parklawn Drive, Rockville, Md. 20857 301-443-4695
N	Subpart D - Grants and Loan Guarantees for Planning & for Initial Development Costs	do	do	do	Sets forth requirements for planning and initial development projects or for significant expansion of the membership of, or areas served by qualified HMOs.	No	do
N	Subpart E - Loans & Loan Guarantees for Initial Operating Costs	do	do	do	Sets forth requirements for the award of loans and loan guarantees for initial operating costs of HMOs.	No	do
F	Subpart F - Qualification of Health Maintenance Organizations	do	do	do	Sets forth requirements for determining whether an entity is a qualified HMO.	No	do

1/ RA - Regulatory analysis (Yes/No)

	Title	Classification	Statutory Base	Need to Regulate	Description	RA[1/]	Contact
N	Subpart G - Restrictive State Laws & Practices	Policy Significant	Title XIII of the Public Health Service Act, as amended	Law requires the development of regulations	Sets forth requirements prohibiting States from establishing or enforcing any law which would prevent an entity from doing business as an HMO.	No	H.Earle Belue Regulations Office, OHMO, Park Building, Room 3-32, 12420 Parklawn Drive, Rockville, Md. 20857 301-443-4695
N	Subpart H - Employees' Health Benefits Plans	do	do	do	Sets forth requirements for certain employers and States and political subdivisions of States to include in any health benefits plans offered to their employees the option of membership in qualified HMOs.	No	do
N	Subpart I - Continued Regulation of HMOs and Other Entities	do	do	do	Sets forth continued compliance requirements for qualified HMOs.	No	do

1/ RA = Regulatory analysis (Yes/No)

	Title	Classification	Statutory Base	Need to Regulate	Description	RA[1/]	Contact
N	(New Regulations on training and technical assistance)	Policy Significant	Title XIII of the Public Health Service Act, as amended	Law requires the development of regulations	To set forth requirements for the development of a training and technical assistance program	No	H. Earle Belue Regulations Office, OHMO, Park Building, Room 3-32, 12420 Parklawn Drive, Rockville, Md. 20857 301-443-4695
N	(New Regulations on Construction)	do	do	do	To set forth requirements for the award of loans to public and nonprofit HMOs and for the award of loan guarantees to private HMOs for the acquisition and construction of ambulatory health care facilities	No	do

1/ RA - Regulatory analysis (Yes/No)

HEALTH CARE FINANCING ADMINISTRATION

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Recodification of Medicare Regulations Dealing with Hospital Insurance Entitlement, Deductible and Coinsurance Requirements.	NPRM	Technical	Secs. 1811, 1812, and 1813 of the Social Security Act.	Department is revising regulations to make them clear, simple, and up-to-date.	This regulation would propose to clarify, simplify, and update existing regulations pertaining to: (1) entitlement to Medicare hospital insurance for certain groups, and (2) the Medicare inpatient hospital coinsurance, the post-hospital extended care coinsurance, and the blood deductible.	No	John L. Russell, Medicare Bureau HCFA, Room 1-W-5, Low Rise Bldg., 6401 Security Blvd. Baltimore, Md. 21235 301-594-8260.
Prospective Reimbursement for Rural Health Clinics	NPRM	Policy Significant	Secs. 1833(a)(3), 1861(v)(1)(A), and 1902(a)(13) of the Social Security Act.	Department is considering new policy and is requesting public comment on proposals.	This regulation would propose prospective methods for reimbursement of rural health clinics under Medicare and Medicaid.	No	Marty Seyler Medicare Bureau, HCFA Room 1-F1 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9015

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Beneficiary Liability for Items or services excluded from Medicare Coverage.	NPRM	Technical	Sec. 1879 of the Social Security Act.	Department is considering change in policy and is requesting public comments on proposals.	This regulation clarifies that a beneficiary can not be found liable for certain non-covered items or services if he has not been notified in writing that the items or services in question are excluded from medicare coverage.	NO	Mendel S. Kaufman Medicare Bureau 127 East High Rise 6401 Security Blvd Balt. Md. 21235 301-594-9232
Prohibition Against Assignment of Claims	Final	Policy Significant	Secs. 1102, 1814, 1815, 1835, 1870, 1871 of the Social Security Act.	Recent changes in law specifically require regulation.	This regulation specifies criteria and procedures to prohibit providers physicians, and other suppliers, with certain exceptions, from assigning claims for reimbursement of services to other persons for collection. It also imposes administrative sanctions against providers, physicians, and suppliers who violate this prohibition.	No	John J. Russell Medicare Bureau 1-H-5 Low Rise Bldg. 6401 Security Blvd Balt. MD. 21235 301-594-9595

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Payments to Foreign Hospitals for Inpatient Services.	NPRM	Technical	Secs. 1814(f)(3) and (4) and 1861 (v) of the Social Security Act.	Department is considering changes in policy and is requesting public comment on proposal.	This regulation would propose procedures and criteria for Medicare payments for covered inpatient services furnished to beneficiaries by foreign hospitals.	No	Hugh J.McConville Medicare Bureau 412 East High Rise 6401 Security Blvd. Baltimore, Maryland 21235 - 301-594-9430
Medicare Payments to Indian Health Service (IHS) Hospitals	Final	Policy Significant	Sec. 1880 of the Social Security Act	Law in general terms; implementing instructions needed.	This regulation provides for Medicare payments for services rendered in IHS Hospitals and skilled nursing facilities.	NO	John B. Russell Medicare Bureau 1-H-5 Low Rise Bldg. 6401 Security Blvd. Baltimore, Maryland 301-594-8260
Health Maintenance Organization (HMO) Contracts	Final	Technical	Sec. 1876(a)(i) and (j) of the Social Security Act.	Law specifically requires regulations.	This regulation establishes requirements for contracts between the Secretary and HMO's participating in the Medicare program. It governs contract application procedures, denials, terminations, renewals, effective dates, responsibilities of the the HMO, rights of the Secretary to inspect and audit the HMO, and changes in ownership of the HMO.	NO	Marinos T. Svolos Medicare Bureau, 106 East High Rise 6401 Security Blvd. Baltimore, Md. 21235 301-594-9314
Reimbursement-Prepaid Health Plans	Final with comment.	Policy Significant	Secs. 1802 and 1833(a)(1)(A) of the Act.	Law specifically requires regulations.	This regulation would establish principles of reimbursement for health care prepayment plans similar to those applicable to health maintenance organizations.	No	Marinos T. Svolos Medicare Bureau 106 East High Rise 6401 Security Blvd., Baltimore, Md. 21235 301-594-9314

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Elimination of the Combination Method of Apportionment for Providers.	Final	Technical	Sec. 1861(v)(1)(A) of the Social Security Act	Department is considering changes in policy and has requested public comments on the proposed regulation.	This regulation modifies the methodology used to determine a provider's reimbursable costs for services furnished to beneficiaries	No	Hugh J. McConville Medicare Bureau 412 East High Rise 6401 Security Blvd Baltimore, Md. 21235 301-594-9430
Payment for Injections and Negotiated Rates for Laboratory Services.	NPRM	Policy Significant	Secs. 1833(a)(1)(D) and 1833(h) of the Social Security Act	Law specifically requires regulation.	This regulation sets a reasonable charge for injection services and for certain diagnostic laboratory tests.	No	Paul Riesel Medicare Bureau 190 East High Rise 6401 Security Blvd Balt. Md. 21235 301-594-9595
Reopening Reimbursement Determinations.	NPRM	Technical	Sec. 1861(v)(1)(A)(ii) of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation would propose criteria for reopening certain provider cost reimbursement determinations.	NO	Mendel S. Kaufman Medicare Bureau 127 East High Rise 6401 Security Blvd Balt, Md. 21235 301-594-9232
Reduction in Grace Period Days Where Payment is Made for Certain Non-reimbursable Expenses	Final	Technical	Secs. 1153(d) and 1879 of the Social Security Act.	Law specifically requires regulation.	This regulation limits reimbursement to only 1 additional day of service after a Medicare beneficiary or provider receives notice that the services are excluded from Medicare coverage. Payments will be made for up to 2 additional days if time is needed to arrange postdischarge care.	No	Mendel S. Kaufman Medicare Bureau 127 East High Rise 6401 Security Blvd Balt, Md. 21235 301-594-9232

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Transactions: Provider Capital Stock.	Final	Policy Significant	Sec.1102 of the Social Security Act.	Department is considering changes in policy and has requested public comments on the proposed regulation	This regulation establishes rules for the treatment of depreciation for purposes of calculating medicare reimbursement, including cases of transfers of corporate stock, mergers and consolidations.	NO	William J. Goeller, Medicare Bureau, HCFA, RM-412,EHR., 6401 Security Blvd., Baltimore,MD 21235, 301-594-9820
Collection of Overpayments to Providers	Final	Policy Significant	Secs.1102,1815, 1870, and 1871 of the Social Security Act and Federal Claims Collection Act of 1966.	Department is considering changes in policy and has requested public comments on the proposed regulation.	This regulation authorizes the Secretary or his designee to compromise claims or to suspend or terminate collection action on claims arising from Medicare overpayments.	NO	Raymond M. Sillup, Medicare Bureau, HCFA Rm. B-2 Gwyn Oak Bldg. 6401 Security Blvd., Baltimore, Md. 21235 301-594-9319
Retroactive Adjustment in Payments to Providers in Case of Erroneous Reimbursement Methods.	Final	Technical	Sec.1861(v)(1)(A)(ii)of the Social Security Act.	Department is considering changes in policy and has requested public comments on the proposed regulation.	This regulation authorizes the Secretary to adjust payment made to Medicare providers under an erroneous method for determining costs.	NO	Lawrence J. Ageloff, Medicare Bureau,HCFA,RM-45 EHR Bldg.,6401 Security Blvd.,Bali,MD.21235 301-594-6719
Allowance for Depreciation Based on Asset Costs.	Final	Policy Significant	Secs.1814(b),1815, and 1861(v)(i) of the Social Security Act.	Law in general terms; implementing instruction needed.	This regulation clarifies and expands existing policy for determining the useful lives of depreciable assets used in the provision of patient care. The regulation also provides for the proper treatment of gains and losses on the disposal of assets.	NO	Hugh H. McConville, Medicare Bureau, HCFA Room 412 East High Rise 6401 Security Blvd. Baltimore, Md. 21235 301-594-9595.

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Definition of Radiological Services.	NPRM	Policy Significant	Sec. 1833(a)(1)(B) of the Social Security Act.	Department is considering a new policy that requires modified regulations and would request public comments on the proposal.	This regulation broadens the scope of the radiology services for which Medicare will be reimburse at 100 pct. of reasonable charges.	No	Paul Riesel, Medicare Bureau, HCFA, Room 412 East High Rise Bldg., Baltimore, Md. 21235, 301-594-9595
Reimbursement: Internship and Residency Programs.	NPRM	Policy Significant	Secs. 1102, 1861(b), 1861(v)(1) and 1903 of the Social Security Act.	Department is considering change in policy and is requesting public comment on proposal.	This regulation would propose to eliminate the requirement that a provider's costs be reduced by the amounts of certain grants and donations when calculating the reimbursement allowed under Medicare, Medicaid or the maternal and child health program. These grants and donations are those which support approved internship and residency programs in family practice, general medicine, and general pediatrics.	No	William J. Goeller, Bureau, HCFA, Room 412, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-9820
Payment for Services of Physicians in Teaching Hospitals, for Physician Costs to Hospitals and Medical Schools and for Volunteer Services.	NPRM	Policy Significant	Secs. 1842(b)(3) and 1861(b)(7)(A) of the Social Security Act.	Law specifically requires regulation.	This regulation proposes criteria under which Medicare would pay reasonable charges for physician services in teaching hospitals or would reimburse teaching hospitals for the reasonable costs of physician services. It would also specify the manner and extent to which payments would be made for certain medical school costs and for services of volunteer physicians	No	Paul Riesel, Medicare Bureau, HCFA, Room 190, East High Rise Bldg., 6401 Security Blvd. Baltimore, Md.21235, 301-594-9595

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
End-Stage Renal Disease Services. Reimbursement for Organ Procurement, Histocompatibility Testing, and Home Dialysis Equipment	Final with comment period	Policy Significant	Sec. 1102, 1814 (b), 1833, 1861 (v)(1), 1871, and 1881 of the Social Security Act.	Recent changes in law specifically require regulation.	The regulation will provide for 100 percent reimbursement for cost of furnishing and maintaining home dialysis equipment, for services furnished by an organ procurement agency or histocompatibility laboratory to obtain and analyze kidneys for transplantation.	No	Hugh McConville Medicare Bureau, HCFA Room 412 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9430
End-Stage Renal Disease: Target Rate Reimbursement	NPRM	Policy Significant	Sec. 1881 of the Social Security Act.	Recent changes in law specifically require regulation.	The regulation would establish an optional target rate reimbursement method for providers and facilities approved to furnish home dialysis supplies and equipment, and home self-dialysis support services to Medicare patients.	No	Hugh McConville Medicare Bureau, HCFA Room 412 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9430
Incentive Reimbursement for End-Stage Renal Disease (ESRD) Services.	NPRM	Policy Significant	Sec. 1881 of the Social Security Act.	Law in general terms, implementing instructions needed.	The regulation would propose methods and procedures for reimbursing providers and facilities for outpatient renal dialysis services provided to ESRD patients.	No	Hugh McConville Medicare Bureau, HCFA Room 412 East High Rise Bldg 6401 Security Blvd., Baltimore, Md. 21235 301-594-9430
Review of Provider Reimbursement Board Decisions	NPRM	Policy Significant	Secs. 1102 and 1878(f)(1) of the Social Security Act.	Law in general terms, implementing instructions needed.	This proposal would specify the criteria and procedures for review of Provider Reimbursement Review Board decisions by the Administrator, HCFA. The amendment is necessary to resolve current confusion concerning the procedures and to comply with the Administrative Procedures Act.	No	Erica L. Gosnell Office of Attorney-Advisor, HCFA Room G-50 Altmeyer Bldg 6401 Security Blvd. Baltimore, Md. 21235 301-594-5132

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Medicare Entitlement Based on End Stage Renal Disease (ESRD)	Revised Final	Technical	Secs.226A and 1881 of the Social Security Act.,	Recent changes in law specifically require regulation.	The regulations will extend Medicare coverage to ESRD patients who are 65 years of age or older permit coverage to begin earlier for patients who receive renal transplants or training in self dealysis and lengthen the duration of Medicare payments following a renal transplant. Comments received in response to publication of final regulation on September 28, 1978, are being considered to determine if revisions are needed.	NO	John Russell Medicare Bureau HCFA,RM-1-H-5, East High Rise Blvd., Baltimore,MD., 21235 301-594-8260
End Stage Renal Disease (ESRD) Services Networks.	NPRM	Policy Significant	Sec. 1881 of the Social Security Act.	Recent changes in law require implementing instructions.	The proposed regulation would require at least one patient representative on each network coordinating council and executive committee. It would also require disclosure of information when network members or thier relatives own or have controlling interest in a renal dialysis facility, or have received compensation in excess of reasonable costs for any services or goods.	No	Cor Denion, Medicare Bureau, HCFA,RM 1-G-3 East Low Rise Bldg. 6401 Security Blvd. Baltimore,MD,21235 301-594-9029

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Cost to Related Organizations	NPRM	Policy Significant	Secs. 1102 and 1861(v)(1)(A) of the Social Security Act.	Department is considering change in policy and is requesting public comments on proposals.	These regulations would clarify existing policy on Medicare reimbursement for services, facilities, and supplies furnished to a provider of services by an organization related to a provider by common ownership or control. They will also codify policy now in program instructions in manuals. This revision supplements the NPRM published on August 17, 1978 on reimbursement to shared services organizations.	No	Bruce Oliver Medicare Bureau, HCFA, Room 440, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-8224
Membership on Carrier Boards	NPRM	Policy Significant	Secs. 1102, 1816 (b), 1842(f)(1), 1871, and 1902 (a)(4) of the Social Security Act.	Department is considering change in policy and is requesting public comments on proposals.	Comments received in response to a notice of intent to limit the number of physicians or other persons with financial interest on the boards of directors of fiscal intermediaries and carriers, published on June 23, 1978, are being evaluated. The regulation would be designed to eliminate potential conflicts of interest.	No	Marty Kappert Medicare Bureau, HCFA, Room 256, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9415
Coverage of End-Stage Renal Disease (ESRD) Services.	Revised Final	Policy Significant	Sec. 1881 of the Social Security Act.	Recent changes in law specifically require regulation.	This regulation defines the specific ESRD services that will be covered and the conditions under which these services must be provided to be reimbursed under Medicare. Comments received in response to publication of final regulation on October 24, 1978 are being considered to determine if revisions are necessary.	No	Hugh McConville Medicare Bureau, HCFA, Room 412 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9430

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Durable Medical Equipment	NPRM	Policy Significant	Sec. 1833(f) of the Social Security Act.	Recent changes in law specifically require regulation.	This regulation would propose criteria for requiring purchase (on a lease purchase or other basis) of an item of durable medical equipment when purchase would be less costly or more practical than rental. Procedures are proposed for waiving the purchase requirement and coinsurance in specific circumstances.	No	Paul Riesel, Medicare Bureau, HCFA, Room 190 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9595
Amendments-Fiscal Intermediaries.	Final	Policy Significant	Secs. 1816 and 1842 of the Social Security Act.	Recent changes in law specifically require regulation.	This regulation recodifies existing regulations dealing with contracts between the Secretary and Medicare fiscal intermediaries. It also specifies standards, criteria, and procedures for determining the efficiency and effectiveness of those intermediaries and for assigning providers to intermediaries.	No	John W. Jansak, Medicare Bureau, HCFA, Room 209, East High Rise Blvd., 6401 Security Blvd., Baltimore, Md. 21235 301-594-8431
Reopening and Revision Claims Determination Under the Medicare Program.	NPRM	Policy Significant	Secs. 1842(b) (3) and (4) and 1869 of the Social Security Act.	Department is considering change in policy and is requesting public comment on proposals.	This regulation would propose to revise and expand the criteria governing the reopening and revision of Medicare benefit payment determinations.	No	John B. Russell, Medicare Bureau, HCFA, Room 1-W-5, Low Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-8260
Conformance with Professional Standards Review Organization (PSRO) Regulations.	Final with comment period	Technical	Secs. 1152(e), 1154(b), 1155(a)(1), 1158, 1164, and 1165 of the Social Securitt Act.	Law in general terms; implementing instructions needed.	These regulations will conform Medicare rules to PSRO regulations which govern responsibilities of PSRO's for determining the medical necessity, quality, and appropriateness of health services for which payment may be made under Medicare.	No	Marinos T. Svolos, Medicare Bureau HCFA, Room 106, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235 301-594-9314.

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Reasonable Charges-Medical Supplies.	Revised Final	Policy Significant	Secs. 1833(g) and 1842(b)(3) of the Social Security Act.	Department has set new policy and has requested public comment on proposals.	This regulation limits reimbursement under the Medicare and Medicaid programs for medical services, supplies, and equipment that do not generally vary significantly in quality from 1 supplier to another. Payments will be based on the lowest charge levels at which the services are widely and consistently available in a locality. Comments are being considered on final regulation published with comment period on July 26, 1978	NO	Paul Riesel, Medicare Bureau, HCFA Room 190, East High Rise 6401 Security Blvd. Baltimore, Md. 21235 301-594-9595
Cost to Related Organizations: Shared Services	Final	Policy Significant	Sec. 1861(v)(i)(A) of the Social Security Act	Department is considering new policy and is requesting public comment on proposals.	The regulation would limit the amount a provider may be reimbursed on the basis of charges when it obtains services facilities, and supplies from an organization related to the provider by common ownership or control.		Bruce Oliver Medicare Bureau, HCFA Room 440 East High Rise 6401 Security Blvd. Baltimore, Md.21235 301-594-8224

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Suspension of Physicians and Other Practitioners	Final	Policy Significant	Secs. 1102, 1862, 1866, 1871, and 1902 of the Social Security Act.	Recent changes in law require implementing instructions.	This regulation establishes criteria and procedures for suspending physicians and other practitioners from the Medicaid or Medicare programs after they have been convicted of a crime related to either program.	No	Irwin Cohen, Office of Program Integrity, HCFA, Room 588 East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-5415
Disclosure of Information and Access to Provider Records (Companion of HDS and PHS regulations)	Final	Policy Significant	Secs. 1124, 1126, 1861, 1866, 1902, 1903, and 2002 of the Social Security Act.	Recent changes in law require implementing instructions.	This regulation specifies criteria and procedures for disclosure by providers of certain information about owners, employees, subcontractors, and suppliers. The regulation also specifies criteria for HEW access to Medicaid provider records.	No	Irwin Cohen, Office of Program Integrity, HCFA, Room 588, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-5415
Uniform Reporting	PPRM	Policy Significant	Secs. 1121, 1861, and 1902 of the Social Security Act.	Recent changes in law require implementing instructions.	Six regulations propose uniform systems that medical institutions which receive payments under the Medicare and Medicaid programs must use for reporting such items as cost of operation, volume of services, reimbursement rates, capital assets, and discharge and bill data.	*	James M. Kaple, Office of Policy, Planning and Research, HCFA, Room 5074, Switzer Bldg. 330 C St., S.W., Washington, D.C. 20201, 202-245-0697

*Under Consideration

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Requirements for End Stage Renal Disease (ESRD) Self-Dialysis Units and Services	Revised Final	Policy Significant	Sec. 1881 of the Social Security Act.	Recent changes in law require implementing instructions.	The regulations establish requirements that self-dialysis facilities and units must meet to be approved to provide services to ESRD patients under Medicare. Comments received in response to final regulations published on October 19, 1978, are being considered to determine whether revision is needed.	No	Janet Harryman, Health Standards and Quality Bureau Bureau, HCFA. Room 301, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-9712
Conditions for Participation: skilled nursing facilities and intermediate care facilities	NPRM	Policy Significant	Secs. 1102, 1814, 1832, 1833, 1842, 1861, 1862, 1863, 1865, 1866, 1870, and 1871 of the Social Security Act.	Department is considering major changes in policy and is requesting public comment	The proposed regulation would recodify, revise, and consolidate present regulations governing participation of skilled nursing and intermediate care facilities.	No	Janice Caldwell, Health Standards and Quality Bureau, HCFA, Room 12A-44, Parklawn Bldg., 5600 Fishers Lane Rockville, Md. 20857, 301-443-3346.
Sprinkler Systems for Long Term Care Facilities	NPRM	Policy Significant	Sec. 1102 of the Social Security Act	Department is considering changes in policy and is requesting public comments	Comments are being evaluated that were received in response to NOI issued on November 14, 1978, that requested comments on alternatives for requiring fire extinguishment systems in all skilled nursing and intermediate care facilities.	No	Janice Caldwell, Health Standards and Quality Bureau, HCFA, Room 12A46, Parklawn Bldg., Rockville, Md. 20857, 301-443-3346

HCFA REGULATION AGENDA

* RA = Regulatory Analysis (Yes/No)

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Professional Standard Review Organizations (PSRO's) Reconsiderations and Appeals	NPRM	Policy Significant	Sec. 1159(a) of the Social Security Act.	Law in general term; implementing instructions needed.	This regulation would propose procedures for the reconsideration of the determinations of PSRO's and the review of such reconsiderations by statewide professional standards review councils.	No	Tony Tirone, Health Standards and Quality Bureau, HCFA, Room 5323, Switzer Bldg., 330 C Street, S.W., Washington, D.C. 20201; 202-245-2156.
Conditions for Coverage for Renal Transplants	Final	Policy Significant	Secs. 226(g) and 1102 of the Social Security Act.	Department has set new policy which requires modified regulations.	This regulation exempts pediatric hospitals from certain renal transplant center certification requirements. Comments received in response to final regulation published with comment period on Aug. 11, 1978 are being considered to determine whether revision is needed.	No	Janet Herryman, Health Standards and Quality Bureau, HCFA, Room 201, East High Rise Bldg., 6401 Security Blvd, Baltimore, MD 21235 301-594-9712.
Histocompatibility Testing	NPRM	Technical	Sec. 1861(a)(10) of the Social Security Act.	Department is considering changes in policy and is requesting public comments on proposals.	These regulations would clarify definitions and techniques for histocompatibility testing carried out under the Medicare program for individuals with end-stage renal disease to determine if a donor kidney will be compatible with recipient.	No	Charlotte Conaway, Health Standards and Quality Bureau, HCFA, Room 324, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-7761.
Revocation of Electrical Requirements	Final	Technical	Sec. 226(g) of the Social Security Act.	Department has set new policy that requires modified regulations.	This regulation revokes requirements for emergency generators and ground fault interrupters in freestanding end-stage renal disease centers because they have proven unnecessary	No	Robert Moore, Health Standards and Quality Bureau, HCFA, Room 361, East High Rise Bldg., 6401 Security Blvd., Baltimore, Md. 21235, 301-594-9731.

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Chiropractors, Physical Therapists, and Speech Pathologist Technical Amendments.	Final with comment period	Technical	Secs. 1861(r) and 1861(s) of the Social Security Act.	Department is considering new policy and requesting public comment on the regulation	The regulations would conform definitions of physical therapist assistant and speech pathologist to other related regulations; clarify requirements for outpatient physical therapy and speech pathology services provided at a home health agency; and provide independent physical therapists and chiropractors the same appeal procedures currently available to other providers.	No	Stefan Miller, Health Standards and Quality Bureau HCFA, Room 349, East High Rise Bldg., 6401 Security Blvd Baltimore, Md. 21235, 301-594-9746.
Validation of Accreditation Surveys of Hospitals	NPRM	Policy Significant	Secs. 1102, 1861(b), 1864, 1865, and 1871 of the Social Security Act.	Department is considering changes in policy and is requesting public comment on proposals.	The proposed regulation would authorize surveys to validate whether Medicare hospitals that have been accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association are meeting the specific Medicare statutory and regulatory conditions for participation	No	Janet Harryman, Health Standards and Quality Bureau HCFA, Room 301, East High Rise Bldg., 6401 Security Blvd Baltimore, Md. 21235, 301-594-9712

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
rofessional Standards Review Organization (PSRO) Review of Intermediate Care Facilities	NPRM	Policy Significant	Sec. 1155(a) of the Social Security Act.	Recent changes in law require implementing instructions.	These regulations would propose conditions under which PSRO's would assume responsibility from State Medicaid agencies for reviewing the quality and necessity of health care services provided in intermediate care facilities and intermediate care facilities for the mentally retarded.	No	Jane Tebbutt Health Standards and Quality Bureau HCFA, Room 16A-27 Parklawn Bldg., 5600 Fishers Lane Rockville, Md., 20857, 301-443-4985.
iver of Liability	NPRM	Policy Significant	Sec. 1158 of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation would propose criteria for determining when a patient or provider would not be held liable for knowing that the services were medically unnecessary or otherwise inappropriate before the services have been disapproved by PSRO's for Medicare and Medicaid payments.	No	Jane Tebbutt, Health Standards and Quality Bureau HCFA, Room 16A-27 Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4985
Redesignation of Professional Standards Review Organization (PSRO) in Illinois	Final	Technical	Secs. 1102 and 1152 of the Social Security Act.	Department has set new policy that requires modified regulations.	This regulation redesignates PSRO areas in Illinois in order to transfer Madison and Clinton Counties (currently in Area VIII) and McConough County (currently in Area V) to Area VII.	No	Steven A. Suerd Health Standards and Quality Bureau, HCFA Room 13A-19 Parklawn Building 5600 Fishers Lane Rockville, Md. 20857 301/443-6477

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Procedures for Hospital Review by Professional Standards Review Organization (PSRO)	Final	Policy Significant	Secs. 1155 and 1156 of the Social Security Act.	Law in general terms; implementing instructions needed.	These regulation would establish procedures for: (1) PSRO review of hospital services for which payment may be made under the Social Security Act; (2) PSRO delegation of review functions to hospitals; and (3) development and use of norms, criteria, and standards for hospital review.	No	Geraldine Ellis, Health Standards and Quality Bureau, HCFA, Room 16A-27, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4654.
Confidentiality and Disclosure of Information of Professional Standards Review Organizations (PSRO's)	NPRM	Policy Significant	Sec. 1166(a) of the Social Security Act.	Law in general terms; implementing instructions needed.	These regulations would propose criteria to govern the acquisition, protection, and disclosure of information obtained or generated by PSRO's.	No	Lois Eberhard, Health Standards and Quality Bureau, HCFA, Room 5121, Switzer Bldg., 330 C St., S. W., Washington, D. C. 20201, 202-245-6712

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Extension of Proficiency Exams for Clinical Laboratory Personnel	Final	Policy Significant	Secs. 1861(s)(11) and 1871 of the Social Security Act.	Department is considering new policy which requires new or modified regulations.	This regulation provides for reopening proficiency examinations for clinical laboratory personnel (technologist, cytotechnologist, and technicians). It eliminates a restriction which prohibited examinations from being given after Dec. 31, 1977.	No	Martha Chesten, Health Standards and Quality Bureau, HCFA, Room 324, East High Rise Bldg. 6401 Security Blvd. Baltimore, Md. 21235, 301-594-7930
Professional Standards Review Organizations (PSRO) Sanctions on Providers and Practitioners	Final	Policy Significant	Sec. 1160 of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation speficies criteria for invoking sanctions against a health care practitioner or provider who claims payment for services which are medically unnecessary or inappropriate do not meet professionally recognized standards, or are not adequately documented as to medical necessity or quality.	No	Tony Tirone, Health Standards and Quality Bureau, HCFA, Room 5323, Switzer Bldg., 330 C St., S.W. Washington, D.C. 20201,202-245-2196.
Funding of Hospital Review by Professional Standards Review Organizations (PSRO's)	NPRM	Policy Significant	Sec. 1861(a) of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation would propose procedures for reimbursing the cost of hospital reviews by PSRO's.	No	Mack Allen, Health Standards and Quality Bureau, HCFA, Room 5311, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-2196

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Safeguards for Patient Funds	Final	Policy Significant	Sec. 1121(m)(1) of the Social Security Act	Recent changes in law require implementing instructions.	This regulation expands standards for protection of personal funds of Medicare and Medicaid patients in skilled nursing facilities and intermediate care facilities.	No	Benjamin Latt, Health Standards and Quality Bureau, HCFA, Room 12A-46, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2420
Termination of Federal Financial Participation in Long-Term Care Facilities	Final	Policy Significant	Secs. 1102 and 1903 of the Social Security Act.	Department is considering new policy which requires new or modified regulations.	This regulation clarifies the circumstances under which Federal funding will no longer be available to skilled nursing facilities or intermediate care facilities under the Medicaid program. It also covers reconsiderations and administrative hearing provisions in State Medicaid plans for those providers whose certification has been terminated.	No	James Conrad, Health Standards and Quality Bureau, HCFA, Room 305, East High Rise Bldg 6401 Security Blvd. Baltimore, Md. 21235, 301-594-9743
Conditions of Participation for Hospitals under the Medicare Program	NPRM	Policy Significant	Sec. 1861(e)(9) of the Social Security Act.	Department is considering significant changes in policy and is requesting public comment on proposals.	This regulation would propose revised conditions for participation in Medicare for hospitals. It would simplify the language, and update the requirements to reflect changes in legislation and advances in technology.	No	Mike Spodnik, Health Standards and Quality Bureau, HCFA, Room 9A-45, Parklawn Bldg., 5600 Fisher Lane, Rockville, Md. 20857, 301-443-4935

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Utilization Review	NPRM	Policy Significant	Sec. 1903(g)(1)(c) of the Social Security Act.	Law in general terms; implementing instructions needed.	The regulation would propose revised requirements and procedures for utilization review in health care institutions participating in Medicare and Medicaid programs. These regulations would provide for review of the medical necessity of admissions and continued stays, the appropriateness and quality of patient care, and the effectiveness of utilization of facility and health professional services.	No	Jane Tebbutt, Health Standards and Quality Bureau, HCFA, Room 16A-27, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4985
Separate Cost Entities and Distinct Parts	NPRM	Technical	Sec. 1861(e), (f), (g), and (j) of the Social Security Act.	Department is considering major changes in policy and is requesting comments on proposals.	This regulation would propose conditions under which a component which provides typically unskilled care within a hospital may be certified as a provider distinct from the hospital.	No	James Conrad, Health Standards and Quality Bureau, HCFA, Room 305, East High Rise Bldg 6401 Security Blvd. Baltimore, Md. 21235, 301-594-7942

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Public Notice of Changes in the Method or Level of Reimbursement for Health Care Services	Final	Policy Significant	Secs. 1102, 1903(a)(4), and 1902(a)(30) of the Social Security Act.	Department implementing new policy in support of anti-inflation effort.	This regulation requires State Medicaid agencies to give 60 days public notice of any proposed change in the method or level of reimbursement for services produced under the Medicaid program. The intent is to allow the Federal Government in cooperation with the States and the public to evaluate the justification for the changes.	No	Milton Dezube, Medicaid Bureau, HCFA, Room 2631, Switzer Bldg., 330 C St., S.W. Washington, D.C. 20201, 202-245-8990
Intermediate Care Facilities/Skilled Nursing Facilities Reimbursement Revisions	NPRM	Policy Significant	Sec. 1102 of the Social Security Act.	Law in general terms; implementing instructions needed	This regulation would propose to clarify and expand requirements for State methods of payment for skilled nursing and intermediate care facility services under State Medicaid programs.	No	Milton Dezube Medicaid Bureau, HCFA, Room 2631, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-8990
Redesignation of Medicaid Administrative Requirements	Final with comment period.	Technical	Sec. 1102 of the Social Security Act.	Redesignation needed to implement organizational changes.	Certain administrative requirements for the Medicaid program are being rewritten to make them more clear and renumbered to move them from 45 CFR Parts 205, 206, and 208 to 42 CFR Chapter IV, Subchapter C, which contains the other Medicaid regulations.	No	Dan Metzman, Medicaid Bureau, HCFA, Room 2618, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-0722
Family Planning	Final with comment period	Policy Significant	Secs. 1903(a)(5) and 1905(a)(4)(C) of the Social Security Act.	Department is considering new policy and is requesting public comment on regulation.	This regulation will specifies Federal requirements for provision of family planning services under Medicaid. It will specify the types and ranges of services that may be included by the States.	No	Barbara Stultz Medicaid Bureau, HCFA Room 2618 Switzer Building 330 C Street, S.W. Washington, D.C. 20201 202-245-9263

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Medicaid Utilization Control	Final	Policy Significant	Secs. 1102 and 1903(g) of the Social Security Act	Recent changes in law specifically require regulation.	This regulation specifies requirements for control over the utilization of inpatient institutional services in the Medicaid program. The regulation also specifies requirements States must meet to avoid reduced Federal matching; the content of quarterly reports; and the methods for making reductions of Federal matching.	No	Phil Otto, Medicaid Bureau, HCFA, Room 3513, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-6557
Timely Claims Processing	Final	Policy Significant	Sec. 1102 of the Social Security Act	Recent changes in law specifically require regulation.	This regulation adds new requirements for timely processing of certain health care providers's claims under Medicaid for payment (90 percent within 30 days of receipt, 99 percent within 90 days). The new requirements are intended to improve program management, increase provider participation in Medicaid, and aid in preventing and detecting fraud.	No	Milton Dazube, Medicaid Bureau, HCFA, Room 2626, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-8990

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
Assignment of Benefits; Collection of Medical Support Payments	Final	Policy Significant	Sec. 1102 of the Social Security Act	Recent changes in law require implementing instructions.	These regulations specify new procedures (1) allowing States to require Medicaid recipients to assign their right to private insurance payments or other medical support to the States; (2) authorizing child support enforcement agencies to assist in collection of medical support; and (3) prohibiting Federal payment to any Medicaid recipient who is covered by a private health insurance policy having a Medicaid exclusion clause.	No	Arthur Muller, Medicaid Bureau, HCFA, Room 2065, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-0384
Medicaid Quality Control Fiscal Disallowances	Final	Policy Significant	Sec. 1102 of the Social Security Act.	Department has set new policy that requires new or modified regulations.	This regulation provides for a reduction in Federal financial participation for erroneous Medicaid expenditures to insure proper use of Federal and State Medicaid funds.	No	Victor Kugajevsky, Medicaid Bureau, HCFA, Room 3094, 330 C St., S.W., Washington, D.C. 20201, 202-245-3846
Medicaid Quality Control Systems: Expansion of Information Requirements.	Revised Final	Policy Significant	Secs. 1102 and 1902(a)(4) of the Social Security Act.	Department has set new policy that requires new or modified regulations.	These regulations expand the Medicaid quality control system for eligibility review to include the extent to which payments for Medicaid services: (a) took account of available medical insurance; and (b) were based on complete and accurate claims. Comments received in response to regulation published on March 31, 1978 are being considered to determine whether a revised regulation should be published.	No	Victor Kugajevsky, Medicaid Bureau, HCFA, Room 3094, 330 C St., S.W., Washington, D.C. 20201, 202-245-3846.

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	*RA	Contact
State Residency Requirements for Medicaid	Final	Policy Significant	Sec. 1102 of the Social Security Act.	Department is considering changes in policy and has requested public comments on proposal.	This regulation establishes new criteria for determining State residency of applicants for Medicaid benefits.	No	Elizabeth Barnes, Medicaid Bureau, HCFA, Room 2625, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-0384.
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Penalty	Final	Policy Significant	Sec. 403(g) of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation specifies standards States are required to meet to insure that EPSDT services are provided to Medicaid eligible individuals under 21. A 1-percent penalty reduction in Federal funding for the aid to families with dependent children program is required if States do not meet the standards.	No	Senora Simpson, Medicaid Bureau, HCFA, Room 4621, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-0111.
General Contract Requirements for Medicaid	NPRM	Policy Significant	Secs. 1102 and 1902(a)(4) of the Social Security Act.	Law in general terms; implementing instructions needed.	This regulation proposes requirements to strengthen protections against questions on contract practices and possible program abuse and to remedy ambiguities and omissions in existing regulations.	No	Pat McCarthy Medicaid Bureau, HCFA, Room 4314, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-0786.
Hearing Aid and Eyeglass Reimbursement	NPRM	Policy Significant	Sec. 1102 of the Social Security Act.	Department is considering changes in policy and has requested public comments on proposal.	Comments received in response to a notice of intent that requested suggestions on practical ways to lower the cost and improve the quality of eyeglasses and hearing aids provided to Medicaid recipients.	No	Larry Rima, Medicaid Bureau, HCFA, Room 2613, Switzer Bldg., 330 C St., S.W., Washington, D.C. 20201, 202-245-9264.

* RA = Regulatory Analysis (Yes/No)

HCFA REGULATION AGENDA

Title	Stage of Development	Classification	Statutory Base	Need to Regulate	Description	RA*	Contact
Fraud in the Medical Assistance Program—Verification of Services	NPRM	Policy Significant	Secs. 1861(k), 1902(a)(30), 1903(g)(1)(C), and 1903(i)(4)	Department is considering new policy and is requesting public comment on proposals.	This regulation would require all States to implement a written verification of services program with Medicaid recipients in order to improve the capability to detect and deter fraud and abuse.	NO	Irwin Cohen Office of Program Integrity, HCFA Room 588 East High Rise Baltimore, Md. 21235 301-594-5415
Withholding Payments to Providers of Services and other Suppliers of Services	NPRM	Policy Significant	Secs. 1102 & 1871	The Department is considering new policy and is requesting public comments on proposals.	This regulation would clarify due process procedures that must be followed when payments to providers, physicians, and suppliers of services under the Medicare program are withheld because of suspected fraud or willful misrepresentation.	NO	Anthony Lovecchio Office of Program Integrity, HCFA Room 532 East High Rise Baltimore, Md. 21235 301-594-9588
Procedures for Recovery of Overpayments and Sanctions: Medicaid Services	NPRM	Policy Significant	Secs. 1102, 1902(a)(4)(A), and 1902(a)(30)	The Department is considering new policy and is requesting public comments on proposals.	This regulation would set forth State plan requirements for States to establish mechanisms for recovery of overpayments in the case of fraud or abuse under the Medicaid program.	NO	Irwin Cohen Office of Program Intregity, HCFA Room 588, East High Ris. Baltimore, Md. 21235 301-594-5415

ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES

Title of Reg.	Classification	Statutory Base	Need to Regulate	Description	RA	Contact
Evaluation Standards NPRM	Technical	Rehabilitation Act (P.L. 93-112) as amended	P.L. 93-112 requires standards; need for accountability	Will establish standards for State VR agency services and operations	No	Kathaleen Arneson, Gregory March Office of Legislation, Regulations & Congressional Relations, RSA Room 3514 Switzer 330 C St, S.W. Washington, D.C. 20201
Section 622 Business Opportunities for Handicapped Individuals NPRM	Policy significant	Comprehensive Rehabilitation Services Amendments of 1978	Law requires regulations within 90 days for this new program	Will provide a frame-work for implementation of the new program	No	"
Child Day Care Standards 45 CFR Parts 71, 220, 223 NPRM	Major	Economic Opportunity Act of 1968 and Title XX (P.L. 93-647)	Regulate day care	To establish standards for day care purchase at a minimum, with Title XX funds	Undecided	Preston Bruce Administration of Children, Youth and Families Washington, D.C. 755-7430 Donohue Building
Removal of $5000 limitation on non-expendable personnel property NPRM	Technical changes	Administrative regulations-no specific statutory base	President's initiative on transportation	This regulation will remove the $500 limitation on the purchase of motor vehicles when they are used for service delivery or administration of the social services	No	Mrs. Johnnie Brooks, Administration for Public Service, HDS, 245-9415
Changes of WIN sanction period to conform with Court Order Part 224.77 Final	policy significant	402(a)(19)(F) of Soc. Sec. Act	A Court Order changing present regulation	Changes sanction period from stated time to that time individual refuses to participate	No	Sheldon Bloom, Dep. Dir., Office of WIN Program 601 "D" Street, N.W. Room 5102 Washington, D.C. 20213 (202) 376-6377

Title	Classification	Statutory Basis	Need to Regulate	Description	R.A.	Contact
45 CFR Part 1304 Child Abuse and Neglect Prevention and Treatment Program Final	Policy Significant	PL. 93-247 (88 Stat 4 et seq.) as amended by PL 95-266	Recent amendments require changes in regulation. Also need to recodify to meet requirements of Operation Common Sense.	Contains various changes affecting operation of the Child Abuse and Neglect Treatment and Prevention Programs including new authority for service programs in addition to previously authorized research, demonstration, evaluation, training, technical assistance, and State grants.	No	James Rich, Policy and Program Specialist, Children's Bureau Administration for Children, Youth and Families, 400 6th St., SW Washington, DC 20201 (202) 755-7553

FOOD AND DRUG ADMINISTRATION

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Allergenic Source Material	Rule	PHS Act	To assure safety and identity of source material	This document prescribes additional criteria for source materials used in the manufacture of a final allergenic product. Specific requirements will be required for the propagation and maintenance of molds and certain animals. Inspection and recordkeeping requirements will apply to all manufacturers of Allergenic Products.	No	A. Rothschild Bureau of Biologics, 11400 Rockville, Pike Rockville, Md. 20852 (301) 443-1307
Additional Standards for Insect Venoms	Proposal	PHS Act	To assure safety and identity of source material	This document proposes requirements for source materials used in the manufacture of allergenic products derived from insect venoms.	No	DO
Additional Standards for Source Materials (Pollens)	Proposal	PHS Act	To assure safety and identity of source material	This document proposes requirements for source materials used for manufacture of allergenic products derived from pollens.	No	DO

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Error and Accident Reports	Proposal	PHS Act	To better assess the adequacy of existing regulations.	This document proposes to require licensed and unlicensed blood establishments to submit reports to FDA of errors and accidents that are imminent health hazards.	No	DO
Commonality of Blood Labeling	Proposal	PHS Act	To facilitate uniformity in blood labeling.	This document proposes to amend the blood labeling regulations as recommended by the American Blood Commission, Committee for Commonality in Blood Banking Automation.	No	DO
Notification of FDA Regarding Adverse Reactions	Proposal	PHS Act	To increase the FDA's effectiveness in regulating biological products.	This document proposes to require that manufacturers notify FDA of reports of adverse reactions from use of their products.	No	DO

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Panel on Review of Bacterial Antigens and Bacterial Vaccines with "No U.S. Standard of Potency"	Rule	PHS Act	To bring products into conformance with current standards of safety and effectiveness.	This document will finalize a proposal, placing the subject products in categories designated as (1) safe and effective and not misbranded, (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products.	No	DO
Panel on Review of Skin Test Antigens	Rule	DO	DO	Do	No	DO
Panel on Review of Allergenic Extracts	Proposal	DO	DO	This document proposes to place the subject products in categories designated as (1) safe and effective and not misbranded, (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products.	No	DO

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Panel on Review of Viral Vaccines and Rickettsial Vaccines	Proposal	PHS Act	To bring products into conformance with current standards of safety and effectiveness.	This document proposes to place the subject products in categories designated as (1) safe and effective and not misbranded, (2) unsafe or ineffective and misbranded, and (3) not within category (1) or (2) above, on the basis that available data are insufficient to classify such products.	No	DO
Panel on Review of Blood and Blood Products	Proposal	DO	DO	DO	No	DO
Panel on Review of Bacterial Antigens and Bacterial Vaccines with U.S. Standard of Potency	Proposal	DO	DO	DO	No	DO

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Antibiotic Certification; Selective testing	rule	Federal Food, Drug and Cosmetic Act	To provide more efficient utilization of the agency's manpower resources and more efficient certification procedures.	Establishes a procedure whereby FDA can eliminate unnecessary duplicative testing in its laboratories.	No.	Ms. Mary McEniry, Bureau of Drugs, (HFD-30), 5600 Fishers Lane, Rockville, MD 301-443-3640. (20857)
Proficiency Testing	proposal	do.	To assure uniformity of results of in vitro dissolution tests among manufacturers.	Requires manufacturers to conduct proficiency testing on their apparatus used in conducting an in vitro dissolution test.	No.	do.
Obligations of Sponsors and Monitors of Clinical Investigations	rule	do.	To provide greater protection of the rights and safety of subjects in clinical investigation and help assure the quality and integrity of the research data used to support the marketing of products regulated by FDA.	Establishes procedures to be followed by a sponsor and a monitor before initiating, and during the course of a clinical investigation involving the use of a drug, medical device, food or color additive, cosmetic, or electronic product.	No.	do.

Significant New Regulations Currently Under Development

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Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Obligations of Clinical Investigators	rule	do.	To provide greater protection of the rights and safety of subjects in clinical investigations and help assure the quality and integrity of the research data used to support the marketing of products regulated by FDA.	Clarifies existing regulations governing conduct of persons who conduct clinical investigations on new drug products and extends the regulations to include persons who conduct clinical investigations on medical devices, food or color additives, cosmetics, and electronic products.	No.	do.
Methadone; Revision of Medical Standards	rule	Federal Food, Drug, and Cosmetic Act and Narcotic Addict Treatment Act of 1974.	Experience with methadone program suggests need to revise standards.	Revises the medical standards for methadone treatment programs by allowing the medical director of a program to exercise greater discretion in applying the required basic clinical standards (for example, on staffing patterns, criteria for admission, and frequency of urine testing). To be published jointly with The National Institute of Drug Abuse.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Abbreviated New Drug Applications for Post 1962 Drugs	proposal	Federal Food, Drug, and Cosmetic Act	To reduce unnecessary human testing of drugs.	Proposes to permit the filing of abbreviated new drug applications for post 1962 drugs by establishing criteria for their submission.	No.	do.
CGMP Regulations for Large Volume Parenterals	rule	do.	To assure a high quality of manufacturing for these products, which are used in seriously ill patients.	Establishes current good manufacturing practices of a class of parenteral drug products that can be characterized as terminally sterilized, aqueous solutions of 100 ml or more.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Requirements for designating the manufacturer's name on a drug or drug product's label	rule	do.	To enable interested persons to determine the relationship of the person whose name is on the label to the product.	Specifies the conditions under which a person may be identified on a drug or drug product's label as its manufacturer. This action revoke's the agency's "man-in-the-plant" policy, which has been used to determine who may be identified on a drug or drug product's label as a manufacturer. Also specifies the qualifying phrases with which packers and distributors could be identified on a drug or drug product's label.	No.	do.
Prescription Drug Labeling	rule	do.	To improve the quality of physician labeling of prescription drugs.	Specifies the content and format of physician labeling for human prescription drugs. The rule designates a required format and provides detailed standards on the kind of information that must be included under each of the specific section headings of the format.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Oral Hypoglycemic Labeling	rule	do.	To update the physician labeling based on current knowledge about these drugs.	Requires additional statements in the labeling of oral hypoglycemics about increased cardiovascular deaths attributed to their use and directs the physician to discuss these risks and alternative therapy with patient.	No.	do.
Ethylene Oxide	rule	do.	Because of possible adverse effects of residues of ethylene oxide and its major reaction products.	Establishes interim residue limits for ethylene oxide and its two reaction products, ethylene chlorohydrin and ethylene glycol, in human and veterinary drug products and medical devices, and maximum daily levels of exposure for drug products where ethylene oxide is used as a sterilant during the manufacturing process.	No.	do.
Fetal Alcohol Syndrome: Required Warning for Drugs Containing Alcohol	proposal	do.	To inform interested persons of the evidence of a causal relationship between alcohol consumption by pregnant women and deformities in their unborn children.	Proposes to require a warning on physician labeling for oral prescription drugs and oral OTC drugs that contain certain amounts of alcohol.	No.	do.

Significant New Regulations Currently Under Development

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Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Oral Hypoglycemic Labeling	rule	do.	To update the physician labeling based on current knowledge about these drugs.	Requires additional statements in the labeling of oral hypoglycemics about increased cardiovascular deaths attributed to their use and directs the physician to discuss these risks and alternative therapy with patient.	No.	do.
Ethylene Oxide	rule	do.	Because of possible adverse effects of residues of ethylene oxide and its major reaction products.	Establishes interim residue limits for ethylene oxide and its two reaction products, ethylene chlorohydrin and ethylene glycol, in human and veterinary drug products and medical devices, and maximum daily levels of exposure for drug products where ethylene oxide is used as a sterilant during the manufacturing process.	No.	do.
Fetal Alcohol Syndrome: Required Warning for Drugs Containing Alcohol	proposal	do.	To inform interested persons of the evidence of a causal relationship between alcohol consumption by pregnant women and deformities in their unborn children.	Proposes to require a warning on physician labeling for oral prescription drugs and oral OTC drugs that contain certain amounts of alcohol.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
FD&C Yellow No. 5	rule	do.	To inform consumers of the presence of FD&C Yellow No. 5 in drug products.	Requires a label declaration on all foods, drugs, and cosmetics containing FD&C Yellow No. 5.	No.	do.
Revision of Investigational Drug and New Drug Application (IND/NDA) Regulations	proposal	do.	To improve the IND/NDA review process and make the approval of new drugs more efficient.	Proposes to rewrite the IND/NDA regulations to more formally structure the IND phases. This would mean if a drug reaches the NDA stage it should be essentially approvable.	No.	do.

Significant New Regulations Currently Under Development

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Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Legal Status of Approved Labeling	proposal	do.	To clarify agency policy in the use of drugs not in accordance with their labeling	Proposes to distinguish between non-labeled and disapproved uses of prescription drugs and the impact of such use in the practice of medicine and in research.	No.	do.
Public Disclosure of Specifications	rule	do.	To ensure that adequate public specifications are available for all drugs.	Provides for the disclosure of specifications submitted to the agency by the manufacturer, unless the specifications serves no regulatory or compliance purpose, and are exempt as trade secrets, and have not previously been publically disclosed.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Requirements for Pediatric Drug Studies	proposal	do.	To ensure that drugs administered to children have been shown to be safe and effective for that use.	Proposes rules under which new drugs that are likely to be used in children will be required to be shown to be safe and effective in children.	No.	do.
Subject Follow-up Regulations	proposal	do.	To improve the protection of subjects participating in drug research	Proposes to require investigators to maintain a list of names and addresses of subjects who participate in investigational studies to provide a means of contacting the subjects in the event data are obtained indicating the need to contact the subject.	No.	do.
OTC Labeling Standards	proposal	do.	To improve the quality of OTC labeling	Proposes to establish standards for OTC labeling. Sets priorities for placement of required information on labels and in labeling; establishes a format for the direction for use and warning; limits space used for unrequired information; and sets type-size requirements.	No.	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Advertising Regulations for Prescription Drug Products	proposal	do.	To improve prescription drug advertising and promotional labeling	Proposes to revise the present regulations to provide clear requirements for modern advertising techniques and to clarify and establish additional requirements for promotional labeling.	No	do.
Policy on Patient Labeling for Prescription Drugs	proposal	do.	To inform patients about the prescription drug products prescribed for them.	Proposes the agency's overall policy on patient labeling for prescription drugs. Contains minimum general requirements for the content, printing specifications, and distribution of labeling and would provide for the availability of guideline labeling to meet the proposed requirements.	Not yet determined	do.

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Umbrella Good Manufacturing Practices (GMP).	Proposal.	Federal Food, Drug, and Cosmetic Act.	To ensure safe manufacturing, processing, packing and holding practices for foods.	This proposal would update and expand the good manufacturing practices regulations for human foods.	No	Mr. Bob Lake, Bureau of Foods (HFF-302), 200 C Street, S.W., Washington, D.C. 20204 (202) 245-1254.
Milk, Cream and Cheese Substitutes.	Regulation.	do	To promote honesty and fair dealing in the interest of consumers.	This regulation would establish standards of identity for milk, cream, and cheese substitutes.	No	do
Smoked Fish GMP.	Proposal.	do	To ensure safe manufacturing practices for smoked fish.	This proposal would revise the GMP regulation for the smoked fish industry.	No	do
Emergency Permit Controls for Acidified Foods, Low Acid Food GMP, Acidified Foods GMP.	Final Regulation.	do	To ensure safe manufacturing, processing, and packing procedures for low acid and acidified foods.	This regulation would establish and revise the specific current food manufacturing processes for acidified and low acid foods respectively.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Standard of Identity for Concentrated Tomato Juice and Concentrated Tomato Products.	Regulation.	do	To promote honesty and fair dealing in the interest of consumers.	This regulation would establish a standard of identity for tomato juice from concentrate and revise the standards of identity for tomato juice and concentrated tomato products.	No	do
Frozen Strawberries Minimum Strawberry Content and Percentage Labeling of Sirup and Dry Sweetener Packs.	Regulation.	do	do	This regulation would establish a minimum strawberry content and percentage labeling of sirup and dry sweetener packs for frozen strawberries.	No	do
Orange Juice with Preservatives Identity.	Final Regulation.	do	do	This final regulation would amend the standard of identity for orange juice with preservatives and concentrated orange juice with preservatives.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Solid Contents Statement on Canned Fruit and Vegetable Products.	Final Regulation.	do	To promote honesty and fair dealing in the interest of consumers.	This final regulation would provide an alternative to drained weight labeling by proposing filled weight labeling requirements.	No	do
Hair Dyes Containing Animal Carcinogen 2, 4TDA, 2NPPD, 2NPAP, and 4COPD.	Proposal.	do	To inform consumers as to the possible dangers regarding these hair dyes.	This document would propose a warning statement on the label of hair dyes containing animal carcinogen 2, 4TDA, 2NPPD, 2NPAP, and 4COPD, if the National Cancer Institute's report confirms that they are carcinogens.	No	do
Hair Dyes Containing Animal Carcinogen 4MMPD.	Final Regulation.	do	do	This final regulation would require a warning statement on the label of hair dyes containing animal carcinogen 4MMPD.	No	do

Significant New Regulations Currently Under Development

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Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Bubble Bath Products Warnings.	Final Regulation.	do	To caution the consumers as to possible problems which may occur while using these products.	On January 28, 1977, a notice was published proposing a required caution statement on labels of cosmetic bubble bath products. The caution statement was proposed in light of many consumer complaints of rashes and genito-urinary tract infactions. The term "bubble bath product" is defined for the purpose of the regulation.	No	do
CTFA Cosmetic Ingredient Dictionary.	Final Regulation.	do	To provide industry with a uniform nomenclature of cosmetic ingredients.	This final regulation would finalize recognition of the CTFA (Cosmetic, Toiletry, and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary, Second Ed., 1976, as petitioned by the CTFA, as a new source of ingredient names adopted for use in cosmetic ingredient labeling. On the initiative of the Commissioner, the document	No	do

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Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				also lists several supplements and new editions of other currently recognized compendia which are proposed for adoption.		
Labeling of Sodium and Potassium Content of Foods.	Proposal.	do	To give the consumers an opportunity to regulate their intake of sodium acid potassium.	This proposal would amend Section 105.69 ("foods used to regulate sodium-- and potassium-- intake") to change the present mode of declaring sodium content and to add a description of how potassium content is also to be declared. There shall also be a new paragraph in Section 101.17 ("Food labeling warning statements") to provide for warnings regarding potassium content on labels of some salt substitutes.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Nutritional Quality Guideline for Fruit or Vegetable Type Beverage Products Requiring Vitamin C.	Final Regulation.	do	To provide consistency in added Vitamin C in these beverages and to provide that such additions are nutriently significant.	This final regulation would establish NQG for fruit or vegetable beverage products containing Vitamin C.	No	do
General Principles for the Addition of Nutrients to Food.	Notice.	do	To provide a guideline by which nutrients could be added to foods in a most appropriate pattern and potency.	This notice would clarify a FDA policy concerning the nutrient fortification of food. This policy is expressed as a series of principles which manufacturers are urged to follow if they elect to add nutrients to a particular food or class of foods.	No	do
Label Statements Relating to Infant Foods.	Final Regulation.	do	To give the consumer the opportunity to know the relative proportions or the principal ingredients in foods for infants.	This final regulation would require percentage declaration of ingredients of infant foods.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
U.S. Recommended Daily Allowance for Manganese.	Proposal.	do	To establish US RDA for manganese so that it can be properly declared as a percentage in foods and supplements.	This proposal would add to the list of US RDA's in Section 101.8(c)(7)(iv) and Section 105.3(b)(1), CFR.	No	do
Revision of Nutrient Specifications for Infant Formulas.	Proposal.	do	To update and clarify the present regulation requirements to reflect current knowledge and, if possible, be consistent with Codex Alimentarius.	This proposal would amend 21 CFR 105.65 ("Infant Foods") to accommodate some changes recommended by the American Academy of Pediatrics in the "standards for (infant) formulas." In this proposal we shall also handle the issue of other nutrients for nutritional adjuncts (e.g., inositol) which are appropriate for addition to infant formulas (and, incidentally, medical foods).	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Specifications for Acceptable Bioavailability of Iron and other nutrients.	Proposal.	do	To assure that iron and other nutrient substances used for nutrient supplement purposes will be nutritionally useful.	The intention of this proposal is to discriminate between acceptable and unacceptable nutrient source compounds or naturally occurring substances on the basis of the nutrient's ability to be absorbed and biologically utilized as a nutrient. Initial action will be to describe the appropriate degree of bioavailability for iron which is to be added to food and the method to determine its bioavailability separately or from a specific food system.	No	do
Upper Limits of Safe Use for Nutritionally Essential Minerals.	Proposal.	do	To provide for safe use of various minerals added to foods and supplements for nutritional purposes.	It is our intention to establish through this proposal upper levels for safe addition of nutritionally essential minerals to foods. Examples of these minerals are chromium, manganese,	No	do

(continued)

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				molybdenum, nickel, selenium, tin, vanadium, copper and zinc. Safety is partly predicated on the nature of the chemical compound which is the vehicle for the respective mineral. Each can be toxic at amounts which may be used in some foods, especially dietary supplements. Unlimited addition of these substances to foods could lead to chronic toxicity.		
Formulated Food Products Used Under Medical Supervision.	Proposal.	do	To provide assurance that these special foods are adequate and appropriate for their specific intended uses.	It is our intention through this proposal to formally classify these formulated food products as "foods for special dietary use" in Part 105, to provide mandatory as well as optional (but desirable) information in the labeling. This regulation might be designed along	No	do

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Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				the lines of Section 105.65 CFR ("Infant foods") although a companion regulation in Subpart C (now "reserved") may be important to describe some special features about the composition and professional literature which would be unique for this class of product. Subpart C might then be titled "Guidelines for quality and labeling."		
Upper Limits Generally Recognized As Safe for Vitamins A and D.	Proposal.	do	To provide a realistic and safe limit for the use, in food and supplements, of these two fat-soluble vitamins which, being stored in the body, can accumulate to produce toxic reactions.	It is our intention to establish through this proposal upper levels of Vitamins A and D in dietary supplements that are considered GRAS and require food additive petitions for higher use levels.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
GRAS-Whey, Whey Products and Hydrogen Peroxide Used in Whey Treatments.	Proposal.	do	To establish safe uses of certain milk proteins.	This proposal would establish common or usual names and affirm the GRAS status for whey and whey products. This is the result of 10 GRAS petitions. These dried whey products have numerous potential uses in food, including sources of milk protein and use as milk solids where not exempted by food standards.	No	do
Use of Chlorine Gas in an Aqueous Solution.	Proposal.	do	To establish safe uses of chlorine as a sanitizing agent.	This proposal would establish GRAS conditions of use for chlorine food sanitizers. This is the result of 12 GRAS petitions for uses of chlorine, hypachlorus acid, and chlorine dioxide as food sanitizing solutions.	No	do
Procedural Regulations for Medical Device Colors.	Proposal.	do	To implement the provisions of the Medical Device Amendments of 1976, as they pertain to color additives.	The Medical Device Amendments were passed in 1976. These proposed regulations for medical devices would amend the color additive regulations to provide for the issuance of regulations	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				listing colors for use in medical devices.		
Proposed Revision of Temporary Tolerances.	Regulation.	do	To update the temporary tolerances for provisionally listed color additives to be consistent with current scientific data.	Section 81.25 prescribes temporary tolerances for the use of certain provisionally listed color additives pending a decision on their "permanent" listing. These were developed on the basis of early preliminary toxicity data. The proposed revision of this section would change the tolerances for most of the colors in Section 81.25.	No	do
Cholesterol-free Egg Substitute—Petition for Reconsideration.	Proposal.	do	To establish consistency in labeling of cholesterol content of foods.	The broad issue of cholesterol labeling needs to be discussed and a policy established. The issue is one that is undergoing considerable study in the Bureau. This proposal deals with the issue of the term cholesterol-free being used in the name of food products.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contract Person
Liquid Protein Products Warning Statement.	Final Regulation.	do	To inform potential consumers of the possible dangers of misuse of liquid protein products.	This tentative final regulation would set forth label warning requirements for protein supplements that may be used in weight reduction or weight maintenance programs.	No	do
Proposal for Common or Usual Name for Diluted Fruit or Vegetable Juice Beverages.	Final Regulation.	do	To provide consistency in the labeling of these beverages especially in respect to juice content.	This final regulation would establish a common or usual name for undiluted fruit or vegetable juice beverages.	No	do
Aflatoxin in Peanuts.	Final Regulation.	do	To prevent avoidable residues of aflatoxins in peanuts and peanut products.	This final regulation would set tolerances for aflatoxin in peanuts.	No	do
Polychlorinated Biphenyles, Proposed Reduction of Tolerance.	Final Regulation.	do	To reduce human exposure to PCB's.	This final regulation will reduce tolerances for PCB's in various foods and feed. It includes proposed reduction of fish tolerance from 5 ppm to 2 ppm.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Infant Food; Junior Food; Toddler Meal.	Final Regulation.	do	To give the consumer the opportunity to know the relative proportions of the principal ingredients in foods for infants.	This final regulation would require percentage declaration of characterizing ingredients as part of the statement of identity. This issue should be resolved as a distinct but related matter to the label statements relating to infant foods.	No	do
Plant Protein—Common or Usual Names for Foods, Vegetable Protein Products which Resemble and Substitute for Meats, Seafood, Poultry, Eggs, or Cheese.	Final Regulation.	do	To provide consistency in the labeling and in the nutrient content of vegetable protein substitutes for the 5 major protein foods.	This final regulation would establish common or usual names for vegetable protein products and names and definitions of nutritional equivalence for the 5 major protein foods.	No	do
Interstate Conveyance on Board Food Service Operations.	Proposal.	Public Health Service Act.	To protect against insanitary conditions on interstate conveyances which carry food in interstate commerce.	This proposal would establish sanitation requirements for interstate conveyances carrying food in interstate commerce.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Interstate Conveyance Catering Point Sanitation.	Proposal.	Public Health Service Act.	To protect against insanitary conditions revolving around catering operations involved with interstate conveyances carrying food in interstate commerce.	This proposal would establish sanitation requirements for caterers to interstate conveyances carrying food in interstate commerce.	No	do
Food Labeling: Designation of Ingredients re: Nutritive Sweeteners.	Proposal.	Federal Food, Drug, and Cosmetic Act.	To provide flexibility in the labeling of sweeteners without depriving the consumer of information.	This proposal is the result of several petitions requesting some form of exemption for identification of specific sweetening ingredient. The broad issue of ingredient labeling of sweeteners in foods as it relates to health and nutrition is one designated for considerable study in the Bureau of Foods	No	do
Common or Usual Name for Substitutes for Margarine or Butter.	Final Regulation.	do	To provide consistency in the labeling of substitutes for margarine or butter.	This final regulation would identify a name like vegetable oil spread. —pet. oil. The butter industry has called attention to the FTC Act	No	do

(continued)

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				which has requirements for labeling margarine. FDA does not define the low fat products as margarine.		
Tolerance for Mercury in Fish.	Final Regulation.	do	To provide a more appropriate action level to permit maximum use of fish without increasing human exposure to mercury.	This final regulation would terminate a proposed regulation and announce the availability of action levels (administrative guidelines) according to new regulations for poisonous or deleterious substances.	No	do
Areas of Principal Display Panel.	Final Regulation.	do	To provide a more uniform basis for determining size and other labeling requirements.	This proposal, which would have revised the definition for the area of the principal display panel which is used for determining type-size and other labeling requirements, is being reconsidered and may be withdrawn.	No	do
Fruit Flavored Spreads.	Final Regulation.	do	To provide consistency in the	This final regulation would establish a common	No	do

(continued)

(continued)

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
			labeling of substitutes for jellies and preserves.	or usual name regulation for fruit flavored spreads.		
Use of Sodium Nitrite in Smoked Fish & Sodium Nitrate in Home Curing Pre-mixes.	Proposal.	do	Data indicate use of nitrate is not needed and that additional safety data is needed for nitrite.	Two documents are being prepared for this issue: (1) a notice of withdrawal of the November 3, 1972 proposal to eliminate certain uses of nitrates and nitrites, and (2) a new proposal to revoke the use of nitrates and nitrites in smoked fish and pet food and to interim list use of sodium nitrite in smoked fish.	No	do
Proposed Regulations for Lakes (pigments).	Proposal.	do	To establish listing regulations for the use of color additive Lakes under the color amendments.	In 1965 a document was published which proposed to list the lakes of the colors. Because of deficiencies in this proposal, we are currently preparing documents to revoke it and request more information on lakes which are now provisionally listed.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
FD&C Red 34.	Proposal.	do	New data indicates the need to prohibit the use of FD&C Red 34.	This document proposes to delist FD&C Red 34 from the permanent list of color additives because of possible contamination by a carcinogen.	No	do
Color Certification— Procedures for Non-conforming Batches.	Proposal.	do	To establish regulations which formalize the procedures used in certification of colors.	This proposal would amend the regulations for the certification of color additives to prescribe procedures for the rejection of samples submitted for certification on the basis of analytical response, when the substance causing the response is unidentified.	No	do
Lead Contamination of Food.	Proposal.	do	To clarify FDA's policy regarding lead contamination of food.	This proposal would be an advance notice of proposed rulemaking which will set out FDA's policy regarding lead contamination of food products.	No	do
Labeling of Yellow No. 5 in Foods and Drugs.	Final Regulation.	do	Scientific data demonstrates the need to establish labeling requirements to (continued)	This final regulation would require the labeling of FD&C Yellow NO. 5 in foods and ingested drugs containing the color (continued)	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
			provide for the safe use of FD&C Yellow No. 5.	because of several documented incidences of allergic-type reactions to FD&C Yellow No. 5		
Use of Food Preservative BHT.	Final Regulation.	do	To re-evaluate the safety of all GRAS food ingredients.	This final regulation would establish an interim food additive level for BHT.	No	do
Annatto Extract, Paprika Oleoresin, and Tumeric Oleoresin.	Final Regulation.	do	New data indicates the need to prohibit the use of the solvent for these color additives.	This final regulation would prohibit use of trichloroethylene as a solvent in these color additives.	No	do
Revocation of Use of Morpholine.	Notice.	do	To expand the scope of a previous proposal.	This notice will withdraw the proposal to revoke the use of morpholine, and a new proposal will issue.	No	do
Chloroform in Contact with Food.	Proposal.	do	New data indicates that the use of this substance should be prohibited.	This proposal would delist certain uses of chloroform in food packaging materials.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Trichloroethylene.	Final Regulation.	do	New data indicates the need to prohibit the use of the solvent.	This final regulation would prohibit trichloroethylene in human food because it may pose a risk of cancer.	No	do
Safety of Certain Food Ingredients: Sucrose and Corn Sugar.	Proposal.	do	To re-evaluate the safety of all GRAS food ingredients.	Proposal would affirm the GRAS status of sucrose and corn sugars.	No	do
Sensitivity of Method	NPRM	do	To facilitate a determination of the safety of drugs intended for food producing animals	This proposal would establish criteria and procedures for evaluating assays for carcinogenic residue in animal derived food	Yes	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Premarket Approval Procedures	Proposal	Federal Food, Drug and Cosmetic Act	Required under Section 515(b)(1)	Provides requirements for submission of premarket approval applications, including safety and effectiveness requirements for all class III medical devices.	No	Mr. Joseph Mamana Bureau of Medical Devices, 8757 Georgia Ave., Silver Spring, MD 20910 (301) 427-7114
Classification of Preenactment Devices	Proposal	do	Required under Section 513(c),(d)	Classifies all medical devices marketed prior to May 28, 1976, into three regulatory control categories. The classifications are based on the recommendations of 8 expert advisory panels.	No	do
Performance Standards Procedural Regulation	Final Rule	do	Needed to implement Section 516.	Prescribes procedures by which performance standards will be established, developed, and promulgated for all class II medical devices.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Banned Device Regulation	Final Rule	do	Needed to implement Section 516.	Provides procedures that FDA can use in banning a medical device that presents a substantial deception or an unreasonable and/or substantial risk of illness or injury.	No	do
Investigational Device Exemptions	Final Rule	do	Required under Section 520(g)(2)(A)	Provides requirements for conducting clinical studies and investigations of medical devices used with human subjects.	No	do
Administrative Restraint Procedures	Final Rule	do	Required under Section 304(g)(1)	Establishes procedures for a 20-30 day administrative detention of medical devices suspected of being adulterated or misbranded.	No	do
Restricted Devices Regulations	Proposal	do	Needed to set forth restricted device standards	Sets forth the criteria for determining which devices are restricted devices	No	do
Mandatory Device Experience Reporting	Proposal	do	To provide FDA with information on devices that are unsafe or ineffective	Sets forth mandatory reporting requirements for manufacturers and distributors for devices that (1) cause or could cause death or injury, or (2) are the subject of a corrective action.	No	do

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
California Application for Exemption from Preemption	Reproposal	do	Response to petition	Responds to California's application for exemption from preemption for its device laws and regulations.	No	do
Applications for Exemption from Preemption for State and Local Hearing Aid Requirements	Final Rule	do	Response to petitions	Responds to 19 State applications for exemption from preemption for hearing aid requirements.	No	do
Procedural Regulation for Medical Device Colors	Proposal	do	Required under Section 706(b)	Amends the color additive regulations to provide for the issuance of regulations listing colors for use in medical devices.	No	Mr. Robert Lake Bureau of Foods 200 C Street, N.W. Washington, D.C. 20204 (202) 245-1254

Significant New Regulations Currently Under Development

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Recommendations Concerning Mammography Screening	NOI	Public Health Service Act	Guidance on when mammography screening is appropriate	Mammography screening of the general population of asymptomatic women has been recommended by various organizations including the American Cancer Society and the American College of Radiology. Because of the potential cancer risks, NIH recently convened an expert committee to review these issues and to develop guidelines for the mammography screening projects being supported by NCI. A Notice of Intent will be published which will seek to obtain information and opinion concerning such questions as the population to be screened, the usefulness of a base-line mammogram, etc. Interim guidelines will also be proposed as part of the Notice. These will be based primarily on the recommendations made by the NIH expert committee.	No	Mr. Michael S. Terpilak Bureau of Radiological Heal 5600 Fishers Lane HEW Rockville, MD 20857 301/443-3426
Diagnostic Ultrasound	NOI	do	To get public opinion on risks of diagnostic ultrasound and appropriate action program	Diagnostic ultrasound equipment is being used widely with little evidence of the degree to which human exposure levels may be harmful, especially to the developing fetus. This notice will announce the potential development of standards and/or recommendations related to the manufacture and use of these devices. The guidance, which is included in the notice, will encourage manufacturers to employ the lowest power levels practicable and will caution against unnecessary exposure to patients and others.	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Nuclear Medicine Quality Assurance of Scintillation Cameras	NOI	do	To minimize radiation exposure while obtaining high quality diagnostic information	Quality assurance procedures, which include quality control procedures, are needed broadly in nuclear medicine to assure maximum benefit from nuclear medical techniques, consistent with obtaining high quality images at minimum cost and minimum radiation dose to the patient. Voluntary recommendations, to be based on BRH technical reports, will be developed in cooperation with representatives of professional, public and private groups that have an interest and knowledge in the field. These recommendations, therefore, would represent a consensus of expert opinion upon which individual practitioners and allied health personnel can rely and would be implemented through educational programs and cooperative activities with professional organizations and State health agencies.	No	do
Recommendations for Diagnostic Examinations	NOI	do	To get public opinion on need and type of action program to narrow range of exposures from diagnostic x-ray procedures	There exists a considerable range in the entrance skin exposure and the resulting organ doses for the same X-ray procedure conducted at different medical facilities and often within the same facility. Radiation exposure recommendations are being investigated that will permit radiologists, radiation protection personnel, and others to evaluate exposure values used in a given facility. Following the analysis of the comments generated by the Notice of Intent, a program decision will be made as to the course of action the Bureau will pursue.	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Recommendation for Routine Chest X-ray Screening for Cardio-pulmonary Disease	NOI	do	To get public opinion on need and content of recommendations concerning use of chest x rays in screening programs	The Bureau is evaluating the use of chest X-ray examinations as part of routine screening programs in the detection of cardiopulmonary disease. Numerous studies have shown that routine chest X-ray screening of asymptomatic persons for certain types of pathology is neither efficacious nor cost effective. The Bureau has prepared a preliminary analysis report evaluating the impact of the Department's 1972 Policy Statement on Routine Chest X-ray Screening.	No	do
National Standards for Medical Radiation Technologists	NOI	do	To get public opinion on present credentialing practices and the need for national standards	This Notice of Intent will be published to announce that the Bureau of Radiological Health will be establishing recommended qualifications for medical radiation technologists. The Notice will solicit professional and public input about existing practices of credentialing, the need for uniform national standards, and possible approaches for ensuring that all medical radiation technologists demonstrate a certain level of competence in conducting medical radiation examinations.	No	do
Phototherapy Recommendations	NOI	do	To minimize risks of ultraviolet radiation exposure in treatment of psoriasis	In this Notice, FDA is announcing that radiation safety guidelines are to be developed and proposed for equipment used as a radiation source (in combination with the drug, psoralen) in the photochemotherapy of psoriasis. Psoriasis is a disfiguring, often incapacitating, disease of the skin		

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				that affects 1 to 3 pct. of the world's population. Derivatives of the drug psoralen are currently being used, along with an ultraviolet radiation source, to treat this disease.		
Recommendation Advocating Use of Improved X-Ray Intensifying Screens	NPRM	do	Reduction of patient exposure by advocating use of high speed x-ray intensifying screens	Recent advances in the manufacture of X-ray intensifying screens offer the opportunity for significant reductions in X-ray exposure to patients for many radiological examinations. The new generation of phosphor materials could enable the performance of many radiological examinations with exposure reductions of one-half or more over previous imaging systems without loss of image quality. It is proposed to develop an FDA radiation protection recommendation designed to encourage rapid adoption of these imaging systems. Such a recommendation, supplemented by performance data on the new intensifying screens, could provide the incentive for facilities to use these newer imaging systems sooner than otherwise would occur.	No	do
Recommendation for Utilization of Skull Radiography Following Trauma	NOI	do	To get public opinion on need and form of action program to eliminate unnecessary skull radiographs	Literature and several clinical studies support the contention that the number of X-ray examinations of the skull for trauma could be reduced by as much as 40 pct. without adversely affecting the quality of health care. The Bureau has prepared a preliminary analysis of the use of skull radiography following trauma, and is supporting a study to survey several clinical facilities to more adequately	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				define the problem. Data from this study will lead to the development of questions and concepts for recommendations which are expected to be published in a Notice of Intent. Following analysis of the comments generated by the Notice, the program will be reviewed and a decision made concerning its future.		
Advisory Opinions and Recodification	Final Rule	do	Clarification and updating of performance standard for diagnostic x-ray equipment	These amendments will codify various interpretations and advisory opinions under which the Bureau currently operates. In addition, the section on assembly and reassembly of diagnostic X-ray systems and components will be moved from § 1000.16 to § 1020.30(p) in order in incorporate the provisions into the body of the standard.	No	do
Recommendations for State and Local Agencies Concerning Accidental Radioactive Contamination of Human Food and Animal Feeds	NPRM	do	To define levels of dose commitments which necessitate protective actions after a release of radioactive material	The proposed recommendation would consist of Protective Action Guides (PAGs), defined as the projected radiological dose equivalent or dose commitment in individuals in the general population that warrants protective action following a release of radioactive material. The Department of Health, Education, and Welfare was assigned agency responsibility for this task in the FEDERAL REGISTER of December 24, 1975 (40 FR 59494) by the Federal Preparedness Agency, General Services Administration. Within HEW, this function has been delegated to the Commissioner of Food and Drugs.	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Regulatory Standard for Mercury Vapor Lamps	Final Rule	do	To reduce risk of ultraviolet radiation exposure from broken mercury vapor lamps	This Agency has decided to develop a regulatory product safety standard for high intensity mercury vapor discharge lamps. A potential radiation hazard associated with the use of such lamps occurs when the outer bulb of the lamp is broken while the inner arc tube of the lamp continues to operate. This results in the emission of hazardous short wavelength ultraviolet radiation. The injury reports received by this Agency further indicate an acute radiation hazard from broken mercury vapor lamps. The standard is intended to reduce the possibility of such injuries by requiring that some performance safety feature be incorporated into the lamp for general lighting purposes so that the lamp will cease operation within a short period of time following the breakage of the outer envelope. Lamps without such a safety feature shall be limited to restricted uses only. Further, adequate information for the safe use of both types of lamps is also required to be provided to the user.	No	do
Amendments to the Performance Standard for Laser Products	Final Rule	do	Clarification and updating of performance standard for laser products	Administration of the laser standard since it became effective on August 2, 1976, indicates that some provisions of the standard may need to be clarified. These changes would reduce, in most cases, the burden on affected manufacturers without compromising the public health. Changes would be made in the measurement provisions, more flexibility would be permitted in	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				labeling, and allowance would be made for the unlikelihood of a potentially dangerous eye exposure to low-level stationary and rapidly scanning laser radiation.		
Regulatory Standard for Microwave Diathermy	NPRM	do	To reduce unnecessary microwave radiation exposure from microwave diathermy equipment	The purpose of this standard is to provide general requirements for microwave diathermy products to assure that to the extent that safety and performance can be controlled, microwave diathermy products are effective for their intended use, and the risk of injury to patient and attending personnel is minimized. The proposed standard includes provisions on minimum microwave radiation output to achieve therapeutic heating, limits on microwave leakage, product interlocks and controls, product performance, labeling, warnings and user instructions, and test requirements.	No	do
Recommendation for X-ray Exposure of Women of Childbearing Age	NPRM	do	To advise physicians on the advisability and methods of minimizing the exposure of pregnant females to diagnostic radiography	The guideline to be proposed will address and explain three particular points in an effort to reduce this risk. It will advise physicians: (a) To ascertain whether their female patients are or could be pregnant, prior to ordering abdominal radiological examinations; (b) to utilize modified or limited studies when possible for female patients who are likely to be or who are definitely pregnant, as a means of reducing fetal exposure; and (c) to use alternative procedures for radiological examinations when appropriate.	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Recommendation for Quality Assurance Programs in Diagnostic Radiology Facilities	Final Rule	do	To reduce unnecessary exposure while improving diagnostic information	The purpose of this publication is to encourage diagnostic radiology facilities to establish their own quality assurance programs with the goals of improving diagnostic image quality and reducing unnecessary patient radiation exposure. The recommendation will also suggest elements which should be included in such programs.	No	do
Amendments to the Diagnostic X-ray Equipment Standard	Final Rule	do	Clarification and updating of performance standard for diagnostic x-ray equipment	Certain of these amendments will codify various interpretations and advisory opinions under which the Bureau currently operates or will clarify the Bureau's intent concerning provisions of the standard. Other amendments concerning spot-film and fluoroscopic X-ray field limitation were proposed in a June 11, 1975, FEDERAL REGISTER Notice of proposed rulemaking (40 FR 24909). As a result of comments received, these latter amendments were withdrawn for further study and are now being reproposed in a modified form.	No	do
Amendments to Diagnostic X-ray Standard Beam Limitation	Final Rule	do	Clarification and updating of performance standard for diagnostic x-ray equipment	These amendments to the diagnostic X-ray standard would revise and simplify the requirements for Positive Beam Limitation (PBL) contained in § 1020.31(e)(2). In addition, provisions for overriding automatic X-ray field adjustment systems on fluoroscopic X-ray equipment will be addressed and a warning label required. The changes in the PBL requirements would allow more flexibility in the	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				conditions under which PBL is required, and should promote more upgrading of old equipment.		
Recommendations or Regulations for Radiation Therapy Equipment	NPRM	do	To improve the use of ionizing radiation therapy through enhanced accuracy of dose delivery	Initiation of a program of quality assurance in therapeutic radiology, principally related to the development of recommendations concerning accurate dose delivery.	No	do
Beam Quality Amendment for Dental X-ray Systems	NPRM	do	Reduction of unnecessary patient exposure in dental radiography	The beam quality amendment for dental X-ray systems would reduce patient exposure resulting from the use of low kilovoltage dental X-ray systems.	No	do
Amendments to the Diagnostic X-Ray Standard Tomographic Systems	NPRM	do	To amend the standard to account for special features of computerized tomographic x-ray systems	Computerized tomographic (CT) x-ray systems are diagnostic x-ray systems which represent a major new technical break-through, not available when the standard was issued. Although some provisions of the standard are appropriate for CT systems, it is recognized that other requirements may not be appropriate for such complex equipment, and that additional requirements may be necessary to assure adequate public health protection.	No	do
Nuclear Medicine Evaluation of Diseases of Thyroid Gland Recommendations	NPRM	do	To lower patient dose in nuclear medicine evaluation of the thyroid gland	Over the past 20 years, increased attention has been drawn to the association between ionizing radiation and the development of nodules and cancer of the thyroid gland. The Bureau is proposing guidance on the need to formulate voluntary recommendations to encourage techniques in nuclear medicine which lower or eliminate patient radiation dose in	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				thyroid studies, without compromising clinical information.		
Suggested State Regulations	Notice of Availability	do	To provide model regulations to State agencies on a wide range of radiation control subjects	State radiation control regulations are essential to effective national protection because they provide protection in areas where Federal agencies have no jurisdiction. The Suggested State Regulations for Control of Radiation was first prepared in 1962 and is periodically updated. A model code, offered through this notice, assists the State in developing their regulation and encourage uniform regulations among States to complement Federal regulations (e.g., in areas beyond certain Federal regulatory authority as in the user area). This is a cooperative project of the Conference of Radiation Control Program Directors (representing the State and local agencies), FDA, and other Federal agencies with responsibilities in radiation control (including the Nuclear Regulatory Commission and the Environmental Protection Agency).	No	do
Regulatory Standard for Sunlamps	Final Rule	do	To minimize ultraviolet radiation exposure related to sunlamps and their use	This standard under development since 1975, is intended to allow continued use of a sunlamp product and yet to minimize the danger of injury. This purpose is achieved through the provisions of safety performance criteria in the standard including the limitation of shorter wavelength emissions, more adequate warnings, requirement of special lamp base and a timer to control the duration of the exposure.	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Emergency Radiation Dose Limits for Health and Safety of Ambulance Services, Hospital and Other Health Care Personnel	NPRM	do	To provide recommended radiation dose limits for emergency workers	Interagency responsibilities for Radiological Incident Emergency Response Planning, Fixed Facilities and Transportation Accidents published in the FEDERAL REGISTER (FR 59191) stated that HEW is responsible for issuance of guidance on emergency radiation doses related to health and safety of ambulance services, hospital and other health care personnel, in cooperation with EPA. The guidance will establish dose limits for emergency medical personnel for planned and unplanned lifesaving actions during the transportation and treatment of persons contaminated with radioactivity. Recommendations will be based on a review of national and international standards relevant to this matter. They will be consistent with present radiation risk and effects information and based on the principle of avoiding unnecessary radiation exposure when possible and that any radiation exposure should be balanced by commensurate benefit.	No	do
Recommendations for Post-Treatment Dental Radiographs	NPRM	do	To reduce the use of dental radiography for non-diagnostic purposes	A practice which appears to be on the increase is the requirement for post-treatment dental radiographs by third party carriers as evidence of dental treatment. Proper justification for the application of radiation to humans requires that there be some potential benefit to the individual receiving the examination. Post-treatment radiographs, however, are not always needed for patient management. It is likely that this	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
				project will culminate in recommendations stating that post-treatment radiographs should not be taken merely as evidence of treatment.		
Recommendations on Radioluminous Timepieces	NPRM	do	To reduce radiation exposure from radioluminous timepieces	Over the past several decades, radium has been used extensively as the luminizing activator in the paint used on the hands and dials of timepieces available to the consumer public. More recently, tritium and promethium-147 have also come into use for this purpose. Radium constitutes a source of unnecessary radiation exposure that could be significantly reduced or avoided by the use of radionuclides emitting lower energy radiations. The proposed recommendations are directed to the State's radiation control program directors and include the efficacy of the luminescence, the occupational exposure parameters, the dose commitment to the individual and population, alternatives to the use of radium, and radiation warning labeling. Because of the responsibilities of other Federal agencies in this area, involvement in the review and development of these recommendations would also include the Nuclear Regulatory Commission, Consumer Product Safety Commission, U.S. Customs, and the Department of Transportation.	No	do
Policy on Assembly and Reassembly of Diagnostic	NPRM	do	To minimize undesirable economic effects of present policy without	This amendment would revoke or extend the effective date of 21 CFR 1000.16(d) which presently requires that only certified components be	No	do

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
X-Ray Systems			adversely affecting the public health	installed into diagnostic x-ray systems which are sold and reassembled after August 1, 1979.		
Radiation Therapy Simulators	NPRM	do	Revision of the performance standard for diagnostic x-ray equipment to account for the special features of radiation therapy simulators	These amendments will codify various interpretations, advisory opinions and variance criteria with respect to radiation therapy simulator systems. They will also bring the standard up to date with new equipment and current usage and practices.	No	do
Microwave Ovens	NPRM	do	To codify various compliance policies as part of the performance standard for microwave ovens	The purpose of this amendment is to bring the language of the performance standard for microwave ovens into conformity with current compliance policy. The specific measuring instrument accuracy would be replaced with a requirement to account for all measurement uncertainties in making compliance measurements.	No	do

By The

Food and Drug Administration

Action	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Sterility & Pyrogencity of Animal Drugs	Notice of Intent	Federal Food, Drug and Cosmetic Act	To assure that all parenteral animal drugs are sterile and free of extrinsic pyrogenic material.	Amends the current good manufacturing practice regulations.	Yes	Robert S. Brigham Bureau of Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (301-443-6243)
Prohibited Substances; Deodorizer Distillates	Tentative Final Regulation	DO	Deodorizer distillate substances have been found to contain concentrated levels of contaminants which are adulterants when added to animal feed.	The regulation would prohibit the use of deodorizer distillates in animal feed.	No	DO
Vitamin K in Animal Feeds	Proposal	DO	Question of general recognition of safety exists regarding certain sources of Vitamin K.	Would propose that only certain Vitamin K substances are generally recognized as safe.	No	DO
Copper in Animal Feeds	Final Rule	DO	Use of high levels of copper in swine and poultry feed raise environmental and tissue residue questions.	Limit the maximum amount of copper compounds in poultry and swine feeds to nutritional levels.	No	DO
Animal Drugs in Minor Species	Proposal	DO	To assure the availability of new animal drugs for minor species for which there is little demand and thus little or no economic value to drug manufacturers.	Modifies the safety and effectiveness requirements for new animal drug approval.	No	DO

Title/Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Drug Carryover in Animal Feeds	Notice	DO	To assure safety of animal feeds and to assure safety of food for human consumption, while recognizing the trace quantities of drugs carried over from batch to batch during manufacture of medicated feeds.	FDA will publish action levels on drugs remaining in feed manufactured in accord with good manufacturing practice when such drugs are the result of carryover of trace quantities of the drug from one feed batch to the next.	No	DO
Definitions of Food Type Animals and Animal Feed	Final Rule	DO	To clearly define the various types and classes of food animals and animal feed, and conditions of approval of such feeds, to assure safe and efficacious use of medicated feeds.	Defines the various types of food type animals and the various types and classes of animal feeds. Modifies the conditions of approval of animal feeds.	No	DO
Approval of Supplemental Applications	Final Rule	DO	To permit FDA to approve supplemental new animal drug applications expeditiously.	In certain instances FDA will approve supplemental new animal drug applications without a complete reevaluation of all safety and effectiveness data in the parent application.	No	DO

By The

Food and Drug Administration

Title of Regulation	Stage of Development	Statutory Authority	Need to Regulate	Description	Regulatory Analysis	Contact Person
Good Laboratory Practices	Final Rule	DO	To assure that nonclinical laboratories follow correct practices.	Establishes criteria for good laboratory practices in non-clinical laboratory facilities.	No	DO
Refusal to Approve Applications	DO	DO	To set forth the type of data acceptable for establishing safety and efficacy of new animal drugs.	Update regulations regarding adequate and well controlled investigations of animal drugs.	No	DO
Revision of Requirements for Appearance and Hearing.	Proposal	DO	To provide a procedure in handling and acting on hearing concerning new animal drug matters consistent with such matters involving drugs for human use.	Revises the new animal drug regulations to make them consistent with the human drug regulations concerning content of the notices of opportunity for hearing and circumstances under which an opportunity for hearing will be granted.	No	DO

IV. EXISTING REGULATIONS CURRENTLY UNDERGOING REVIEW AND REVISION WITHIN THE DEPARTMENT

Office of the Secretary

Title of Regulation	Stage of Development	Contact Person	Citation	Summary
1. State plan procedural rules for the Medicaid, Child Support Enforcement, Title XX Social Services programs, as well as social services and financial assistance under Titles I, IV-A, X, XIV, and XVI(AABD) of the Social Security Act. (45 CFR Parts 201 and 213; 45 CFR §§ 204.1, 204.2, 205.5(b).).	Final	Mr. Beverly Dennis, III, HEW, Room 716-E, 200 Indep. Ave., S.W. Washington, D.C. 20201 (202)245-6648	Titles I, IV-A, IV-D, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act.	These regulations cover State plan processing requirements for providing medical assistance, social services, enforcement of child support, and financial assistance under the Social Security Act. They cover how to submit or amend a State plan; how a claim for Federal funds is allowed deferred or disallowed; what kinds of Federal reviews are conducted; and various State appeals from Federal decisions.

EXISTING REGULATIONS CURRENTLY UNDERGOING REVIEW AND REVISION WITHIN THE DEPARTMENT

Office of the Secretary

Title of Regulation	Stage of Development	Contact Person	Citation	Summary
2. Federal Interagency Day Care Requirements Regulations.	NPRM	Mr. Ralph Susman, Room 305-F, HEW, 200 Indep. Ave. S.W. Washington, D.C. 20201 (202)472-5243	Sec. 577(b) of the Community Services Act of 1974 and sec. 2002(a)(9)(B) of title XX of the Social Security Act.	These regulations establish day care standards which will apply to day care services provided under titles XX, IV-B, IV-A, and IV-A/WIN programs. They also establish administrative provisions to carry out the new standards.

OFFICE OF EDUCATION

Title of Regulation	Stage of development	Contact Person	Citation	Summary
1. Title III - Strengthening Developing Institutions	Final	Dr. Anita Allen, Room 3058 ROB-3, 7th and D Sts. S.W. Washington, D.C. 20202 245-9754	Sec. 301-306 of title III of the Higher Education Act of 1965 as amended.	Under the authority of title III of Higher Education of 1965, the Commissioner assists certain institutions of higher education to strengthen their academic quality and administrative capacity. These institutions are called developing institutions.
2. General Provisions for Education Programs.	NPRM	Mr. Richard G. Bull Room 5082 ROB-3 7th & D Sts. S.W. Washington, D.C. 20202 245-8882	Not Applicable	These regulations contain general administrative and fiscal requirements for direct project grants, contracts, and State-administered programs. Their revision is related to the Department's general regulations for the administration of grants.
3. Pt. 177-Guaranteed Student Loan Regulation	Final	Mrs. Patricia Hopson Room 4642 ROB-3 400 Maryland Ave. S.W. Washington, D.C. 20202 472-3390	Pub. L. 95-43 (amendments)	These regulations contain requirements for both loan guarantee programs of State and nonprofit agencies and the Federal insured student loan program.
4. Basic Education Opportunity Grant Regulations	Final	Mr. William Moran Room 4923, ROB-3 400 Maryland Ave.S.W. Washington, D.C. 20202 245-1744	Title IV of the Higher Education Act of 1965, as amended.	These regulations contain technical requirements to define more clearly the administration of the program and to implement the requirements mandated by the Education Amendments of 1976.

Title of Regulation	Stage of development	Contact Person	Citation	Summary
5. Health Education Assistance Loan Regulations	Final	Mr. David C. Bayer Room 4642, ROB-3 400 Maryland Ave S.W. Washington, D.C. 20202 472-2765	Health Profession Educational Assistance Act of 1976.	These regulations govern a Federal program of insured loans to graduate students in health professional sc schools.
6. Education Amendments of 1978	NPRM	Mr. Larry Koziarz Room 2129, FOB-6 400 Maryland Ave. S.W. Washington, D.C. 20202 472-7580	Education Amendments of 1978	These regulations govern existing Office of Education programs that are affected by the Education Amendments of 1978. Regulations affected include Title I of the Elementary and Secondary Education Act of 1965 and School Assistance for Federally Affected Areas (SAFA)

FOOD AND DRUG ADMINISTRATION

Title of regulation	Stage of development	Contact person	Citation	Summary
1. Administrative Practices and Procedures Regulations (20 CFR).	NPRM for all parts.	Mr. Ronald J. Wylie, Chairman, FDA Operation Common Sense Task Force, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, 443-3480.	Persons desiring specific citations statutory authority should contact Mr. Ronald J. Wylie, Administrative Procedures Act, Public Health Service Act.	These regulations govern practices and procedures applicable to all petitions, formal and informal public hearings, and other administrative proceedings and activities.
(a) Pt. 10—Administrative Practices and Procedures.	do	do	do	Do.
(b) Pt. 12—Formal Evidentiary Public Hearing.	do	do	do	Do.
(c) Pt. 13—Public Hearing before a public board of inquiry.	do	do	do	Do.
(d) Pt. 14—Public Hearing before a public Advisory Committee.	do	do	do	Do.
(e) Pt. 15—Public Hearing before the Commissioner.	do	do	do	Do.
(f) Pt. 16—Regulatory Hearing before the Food and Drug Administration.	do	do	do	Do.
(g) Pt. 19—Standards of Conduct and Conflicts of Interest.	do	do	do	Do.
(h) Pt. 20—Public Information.	do	do	do	Do.
(i) Pt. 21—Protection of Privacy.	do	do	do	Do.
2. Food Labeling Regulations (20 CFR pt. 101).	do	do	Persons desiring specific citations to statutory authority should contact Mr. Ronald J. Wylie, Fair Packaging and Labeling Act, Food and Drug Act.	These regulations contain a variety of key food labeling provisions, including those pertaining to imitation and substitute foods, safe and suitable ingredients, and percentage ingredient labeling.
(a) Subpt. A—General Provisions.	do	do	do	Do.
(b) Subpt. B—Specific Food Labeling Requirements.	do	do	do	Do.

Title of Regulation	Stage of Development	Contact Person	Citation	Summary
Medicaid Residency	Final	Ms. Elizabeth Barnes Room 2627 330 C Street, S.W. Washington, D.C. 20201 (202)245-0534	Title XIX of the Social Security Act	These regulations govern the determination of the State of Residence for Medicaid applicants and recipients.
Conditions of Participation for Hospitals	NPRM	Ms. Janet M. Harryman Room 301 East High Rise Building 6401 Security Blvd. Baltimore, Md. 20235 (301)594-9712	Titles XVIII & XIX of the Social Security Act	These regulations specify the health and safety requirements that hospitals must meet to participate in the Medicare & Medicaid programs.
3. Conditions of Participation for Skilled Nursing Facilities (SNFs) & Intermediate Care Facilities (ICFs).	NPRM	Ms. Constance A. Conrad Room 300 East High Rise Bldg. 6401 Security Blvd. Baltimore, Maryland 21235 (301)594-9722	Titles XVIII and XIX of the Social Security Act	These regulations govern the participation of SNFs and ICFs in the Medicare and Medicaid programs.
4. Medicare Entitlement, Deductible & Co-payment Requirements	NPRM	Mr. John B. Russell Room 1-H-5 East Bldg. 6401 Security Blvd. Baltimore, Md. 21235 (301)594-8260	Title XVIII of the Social Security Act	These regulations govern beneficiaries participation for the Medicare program.

Title of Regulation	Stage of Development	Contact Person	Citation	Summary
1. Fair Hearing Regulations	NPRM	Mrs. Johnnie Brooks Administrator for Public Services P.O. Box 1923 Washington, D.C. 20013 (202) 245-9415	42 U.S.C. 1302	These regulations provide procedures for hearings for persons who are denied services or benefits.
2. Child Abuse & Neglect Prevention and Treatment	NPRM	Mr. Douglas Besharov National Center on Child Abuse and Neglect/Children's Bureau, ACYF/HDS, P.O. Box 1182 Washington, D.C. 20013 (202) 755-0587	The Child Abuse Prevention & Treatment Act of 1974, as amended	These regulations contain requirements for grants and contracts for demonstration and service programs and projects.

PUBLIC HEALTH SERVICE

Title of regulation	Stage of development	Contact person	Citation	Summary
2. PHS Grants Regulations	NPRM	Mr. Richard Cummings, Public Health Service, Room 17B-03, Parklawn Bldg., 5600 Fishers Lane, Rockville, Md. 443-6330	The Public Health Service Act.	These regulations contain provisions for the award of grants under various PHS programs. The Public Health Service is now exploring ways to consolidate all its grants regulations.
(a) Part 51—Grants to States for Comprehensive health planning and public health services, Subpart B.	NPRM	do	do	Do.
(b) Part 51a—Grants for maternal and child health and crippled children services.	NPRM	do	do	Do.
(c) Part 51b—Grants for Communicable Disease Control.	NPRM	do	do	Do.
(d) Part 51c—Project Grants for Health Services development.	NPRM	do	do	Do.
(e) Part 51d—Grants for service projects for cancer and other diseases.	NPRM	do	do	Do.
(f) Part 51e—Grants for home health services.	NPRM	do	do	Do.
(g) Part 52—Grants for research projects.	NPRM	do	do	Do.
(h) Part 52a—National Heart and Lung Institute Grants for National Research and Demonstration Centers.	NPRM	do	do	Do.
(i) Part 52b—National Cancer Institute Construction Grants.	NPRM	do	do	Do.
(j) Part 52c—Minority Biomedical support program.	NPRM	do	do	Do.
(k) Part 52d—National Cancer Institute clinical cancer education program-Minority Biomedical support program.	NPRM	do	do	Do.
(l) Part 52e—National Heart and Lung Institute.	NPRM	do	do	Do.
(m) Part 53—Grants, loans and loan grantees or construction and modernization of hospitals and medical facilities.	NPRM	do	do	Do.
(n) Part 54—Grants for community mental health centers.	NPRM	do	do	Do.
(o) Part 54a—Grants to States for drug abuse and alcoholism prevention, treatment, and rehabilitation services.	NPRM	do	do	Do.
(p) Part 54b—Grants to States for drug abuse prevention functions.	NPRM	do	do	Do.
(q) Part 55—Grants for advancement of health in coal mining.	NPRM	do	do	Do.
(r) Part 55a—Program grants for coal miners' respiratory clinics.	NPRM	do	do	Do.
(s) Part 56—Grants for emergency medical services systems.	NPRM	do	do	Do.
(t) Part 56a—Grants for emergency medical services systems.	NPRM	do	do	Do.
(u) Part 57—Grants for construction of health research facilities (including mental retardation research facilities), teaching facilities, student loans, education improvement and scholarships. Subparts A-C, I-J, K, M, O-P, R-X and BB.	NPRM	do	do	Do.
(v) Part 59—Grants for family planning services.	NPRM	do	do	Do.
(w) Part 58a—National Library of Medicine grants.	NPRM	do	do	Do.

Mr. George Lewis,
Room 17B-03,
5600 Fishers Lane
Rockville, Md.
20857 (301) 443-6330

Title of Regulation	Stage of development	Contact Person	Citation	Summary
1. Federal Old-Age Survisors and Disability Insurance (20 CFR Part 404)	NPRM	Ms. Eve Hilgenberg 4212 West High Rise Bldg. Room 400 Social Security Administration Baltimore, Md. 21235 (301)934-6695	Title II of the Social Security Act as amended	These regulations implement title II of the Social Security Act. Title II provides benefits to retired or disabled workers, their dependents, and to surviving dependents of workers who have died. The funds to pay these benefits are provided from the Social Security trust funds.
(a) Subpart B - Quarters Coverage and Insured Status	NPRM		do	do
(b) Subpart D - Old-Age Disability. Dependents and Survivors Insurance Benefits. Period of Disability	Final		do	do
(c) Subpart G - Filing of Applications and other forms	Final		do	do
(d) Subpart I - Maintenance and Revision of Records of Wages and Self-Employment Income	Final		do	do
(e) Subpart J - Procedures, Payment of Benefits and Representatives of Parties	NPRM		do	do

SOCIAL SECURITY ADMINISTRATION

Title of Regulation	Stage of Development	Contact Person	Citation	Summary
(f) Subpart K-Employment Wages-Self-Employment Self-Employment Income	NPRM	do	do	do
(g) Subpart N-Veterans	NPRM	do	do	do
(h) Subpart P - Rights and Benefits Based on Disability	NPRM	do	do	do
2. Supplemental Security Income for the Aged Blind, and Disabled (20 CFR Part 416)	NPRM	do	Title XVI of the Social Security Act.	These regulations implement title XVI of the Social Security Act. Title XVI provides supplemental security income benefits to aged, blind, and disabled individuals who meet certain income and resources requirements. The funds to pay these benefits come from the general revenues of the U.S. Treasury.
(a) Subpart B-Eligibility	NPRM	do	do	do
(b) Subpart C-Applications	NPRM	do	do	do
(c) Subpart I-Determinations of Disability or Blindness	NPRM	do	do	do
(d) Subpart J-Relationship	NPRM	do	do	do

Title of Regulations	Stage of Development	Contact Person	Citation	Summary
)Subpart K-Income and Exclusions	NPRM	do	do	do
)Subpart N-Determinations, Reconsiderations, Hearings, Appeals and Judicial Review	NPRM	do	do	do
)Subpart O-Representation of Parties	NPRM	do	do	do

Office of Child Support Enforcement

Title of regulation	Stage of development	Contact person	Citation	Summary
1. Child Support Enforcement (45 CFR 232.20 and 45 CFR Chapter III, except for Part 305).	~~NOI~~ NPRM	Ms. Suzanne Duval, Office of Child Support Enforcement, 330 C St. SW., Washington, D.C. 20201, 472-4510.	Title IV-D of the Social Security Act, as amended.	These regulations implement title IV-D of the Social Security Act. Title IV-D contains provisions for the enforcement of support obligations owed by absent parents to their children, locating parents, establishing paternity and obtaining child support.

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